UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CASE NO.:

MSP RECOVERY CLAIMS, SERIES LLC, a Delaware series limited liability company, MSPA CLAIMS I, LLC, a Florida limited liability company, and SERIES PMPI, a designated series of MAO-MSO RECOVERY II, LLC, a Delaware series limited liability company,

Plaintiffs,

v.

TAKEDA PHARMACEUTICALS AMERICA, INC. a Delaware profit corporation; TAKEDA PHARMACEUTICALS U.S.A., INC., f/k/a TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., a Delaware profit corporation; TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC., a Delaware profit corporation; TAKEDA PHARMACEUTICALS INTERNATIONAL, INC., a Delaware profit corporation; TAKEDA PHARMACEUTICAL COMPANY LIMITED a Japanese corporation; and ELI LILLY & COMPANY, an Indiana profit corporation.

Defendants.

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PLAINTIFFS' COMPLAINT FOR DAMAGES

Plaintiffs, MSP Recovery Claims, Series LLC ("MSPRC"), MSPA Claims I, LLC ("MSPA"), and Series PMPI, a designated series of MAO-MSO Recovery II, LLC, ("MAO-MSO"), bring this action for damages[1] against Defendants, Takeda Pharmaceuticals America, Inc.,

[1] This action does not include the claims within MDL No. 2299 and that were part of the settlement between Plaintiffs, Defendants and the Garretson Resolution Group.

("TPA"), Takeda Pharmaceuticals U.S.A., Inc., f/k/a Takeda Pharmaceuticals North America, Inc. ("TPA USA"), Takeda Global Research & Development Center, Inc., ("TGRDC"), Takeda Pharmaceuticals International, Inc., ("TPI"), Takeda Pharmaceutical Company Limited ("TPCL") (collectively, "Takeda"), and Eli Lilly & Company ("Eli Lilly") (collectively referred to as "Defendants"), and state the following:

I. NATURE OF THE ACTION

1. Plaintiffs Assignors, which include Medicare Advantage Organizations ("MAOs"), first-tier and downstream entities, irrevocably assigned, transferred, conveyed, set over and delivered to Plaintiffs, any and all of Assignors' right, title, ownership and interest in and to any and all legal or equitable rights to pursue and recover monies related to the claims that Assignors paid for part or all of their Enrollees' purchases of the prescription drug Actos (pioglitazone hydrochloride).

2. Actos is one of two thiazolidinediones ("TZD" or glitazones) that, on July 15, 1999, received approval by the Food and Drug Administration ("FDA") as an oral antidiabetic agent ("OAD") which acts primarily by increasing cell insulin sensitivity. TZDs lower the blood sugar levels of persons with diabetes through a peroxisome proliferator-activated receptor ("PPAR")[2]. Actos is recommended and prescribed for the management of Type II diabetes mellitus, also

[2] There are several different kinds of PPARs: alpha, gamma, delta, and dual/mixed. Actos was originally considered to be primarily just a PPAR gamma activator, or "agonist." Each PPAR influences different DNA sections and gene expressions which then have different downstream effects within the cell and the body general. PPAR gamma, the primary target of TZDs, lowers insulin resistance and blood glucose levels. PPAR alpha activation, on the other hand is associated with lowering LDLs ("bad" cholesterol) and raising HDLs ("good" cholesterol). Dual agonists activate more than one PPAR, for example activating both alpha and gamma PPARs, thus initiating downstream effects related to both.

known as non-insulin-dependent diabetes mellitus ("NIDDM") or adult-onset diabetes. Millions of individuals in the United States have used Actos to treat their Type II diabetes.

3. Defendants Takeda and Eli Lilly promoted the idea that Actos lowered LDL cholesterol levels and raised HDL cholesterol levels thereby improving the overall health of the patient. Defendants Takeda and Eli Lilly made this claim because Actos was shown, in addition to activating PPAR gamma, to also activate PPAR alpha. Since PPAR alpha activation is associated with improving cholesterol profiles, Defendants Takeda and Eli Lilly used this fact to claim that Actos provided, in addition to improving insulin sensitivity, improved cholesterol benefits.

4. Although Actos lowers LDL cholesterol levels, it does not enhance the health of persons with diabetes. The drug actually increases one's chances of bladder cancer. *See* "Assessing the Association of Pioglitazone Use and Bladder Cancer Through Drug Adverse Event Reporting", Diabetes Care, 34:1369-1371 (June 2011)[3].

5. Actos users can also develop congestive heart failure, hypoglycemia, hepatic effects, macular edema, bone fractures, and macrovascular outcomes. Hence, while use of Actos may lower LDL cholesterol levels of a person with diabetes, it does so at great risks.

6. According to a December 31, 2018, report from the FDA Adverse Event Reporting System (FAERS), more than 18,604, reports of serious cases including, 2,624 death cases associated with Actos were received.

[3] This study looked at the adverse event reports made to the FDA between 2004 and 2009 and analyzed the association between anti-diabetic drugs and bladder cancer. This study concluded that "[i]n agreement with preclinical and clinical studies, AERS analysis is consistent with an association between pioglitazone and bladder cancer. This issue needs constant epidemiologic surveillance and urgent definition by more specific studies." The study found that one-fifth of the 138 bladder cancer reports for all drugs submitted between 2004 and 2009 were regarding patients taking Actos.

7. However, to increase the sales of Actos, Defendants Takeda and Eli Lilly embarked on a comprehensive and carefully orchestrated scheme to promote Actos's safety, efficacy and effectiveness through a fraudulent and deceptive marketing program. In addition to the thousands of people who died or suffered serious injury as a result of their use of Actos, third-party payers such as Plaintiffs' Assignors, who paid for the drug, also fell victim to Defendants Takeda's and Eli Lilly's wrongful scheme to promote and market Actos.

8. Defendants Takeda and Eli Lilly: (a) deliberately misrepresented the scientific, medical and clinical data concerning the safety, effectiveness, and superiority of Actos over comparable drugs; (b) suppressed or mischaracterized negative studies relating to Actos; and (c) caused false and misleading presentations concerning Actos's safety, efficacy and lack of purported side effects to be made to physicians and those paying for Actos, including Plaintiffs' Assignors.

9. Since 1993, Defendant Takeda had discussions with Upjohn Company, a pharmaceutical company with an established presence in the United States and familiarity with FDA regulations and protocols, to partner on Actos' development but, declined to do so because after pre-clinical animal trials it was determined that "further clinical development of pioglitazone could not be justified based on their concern regarding pioglitazone's margin of safety."[4] In response, Defendant Takeda asked Upjohn to frame their decision to withdraw participation in developing Actos as a "business decision" based on a weak glucose reduction efficacy instead of disclosing the safety-toxicology issued raised by the animal trials conducted. Defendant Takeda's

[4] In a letter dated September 21, 1993, Upjohn informed Takeda that it was not going to proceed with developing Actos because of the safety concerns associated with pioglitazone.

letter to Upjohn proposing alternative language as it pertains to Upjohn's development status specifically stated:

> In the very preliminary clinical evaluation in the U.S.A., pioglitazone did not show the reduction of blood glucose enough to satisfy Upjohn's in-house requirement. Any considerable work that would be needed is not in line with business needs for further development of Pioglitazone. Hence, all development on pioglitazone at Upjohn has ceased.

10. Thereafter, on February 6, 1996, Defendant Takeda's Senior Research Head, T. Suzuki, sent the results of a completed rat study for Actos to Dr. Kiyoshi Kitazawa, the General Manger of Takeda in Japan and the lead Takeda contact on Actos development. The study showed abnormal bladder cell and tumor formation in male and female rats, male mice, plus a kidney tumor in a female mouse. In addition, the study showed an increase in "transitional cell" carcinomas[5] in male rats.

11. In an effort to address this alarming bladder cancer data, Defendant Takeda enlisted the help of Dr. Sam Cohen from the University of Nebraska Medical Center. Dr. Cohen attempted to devise an explanation of how rats exposed to Actos were getting bladder cancer that did not also implicate a similar risk to humans. This resulted in what has become known as the "Cohen

[5] Transitional cell carcinoma (also known as urothelial cell carcinoma) is a type of cancer that typically occurs in the urinary system, i.e., the kidney, urinary bladder, and accessory organs. This type of cancer is distinct from squamous-cell carcinoma, which is a cancer that emerges in the epidermis of skin-type tissue and is one of the major forms of skin cancer. However, since squamous cells are also present in the lining of the bladder, digestive tract, lungs, and other areas of the body, squamous-cell carcinoma occurs as a form of cancer in diverse tissues such as the lips, mouth, esophagus, urinary bladder, prostate, lung, vagina, and cervix, among others. Although these two types of cancer are caused by different carcinogens, both can occur in the bladder, although squamous-cell carcinomas are rare and are usually associated with an obvious irritant like a catheter.

Hypothesis"[6] which was presented in a White Paper prepared by Dr. Cohen for Defendant Takeda to provide to the FDA.

12. However, the Cohen hypothesis was a sham theory. That is, it was designed to hide the observed bladder cancer risks associated with Actos. The cancer cells observed in the rat and mice studies were "transitional" cancer cells, generally caused by exposure to a carcinogen in the urine. The Cohen hypothesis, which was predicated on a crystal-irritation mechanism, could only explain the formation of squamous cancer cells, which are caused by direct irritation, and thus, failed to explain why rats and mice developed transitional cancer cells, hyperplasia and hypertrophy unrelated to crystal formation, i.e., transitional cell carcinoma and its precursors.

13. Despite this knowledge, Defendants Takeda and Eli Lilly embraced the Cohen hypothesis and submitted Cohen's White Paper to the FDA as part of Actos' pre-approval materials. Defendant Takeda used the Cohen hypothesis to explain away the rat bladder cancer findings and streamline approval for humans.

14. Thus, although Defendant Takeda had longstanding knowledge of the dangers associated with Actos, including significant bladder cancer, Defendants Takeda and Eli Lilly engaged in a nationwide, uniform marketing campaign involving misstatements regarding Actos' safety and efficacy, deliberately concealing these dangers in order to promote Actos.

15. Further, Defendants Takeda and Eli Lilly concealed and failed to properly and adequately disclose adverse events to Plaintiffs' Assignors.

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[6] The Cohen hypothesis posits that, when rats are exposed to Actos, it alters the pH level of male rats' urine which, in turn, leads to the formation of crystals. These crystals cause excess irritation in the bladder lining of the rat and leads to the formation of bladder cancer. Dr. Cohen explains that this condition would not affect humans because the formation of cancer-inducing crystals was particular to male rats. In addition, due to the way urine is retained by rats, it allows these crystals to irritate the cells lining the bladder. This urine retention did not occur in humans the same way.

16. Defendant Takeda and Eli Lilly also made misrepresentations regarding Actos' safety and efficacy as compared to older medications to the healthcare community, consumers, third-party payors, and others, with the goal of increasing sales and market share of Actos to increase profits.

17. The financial success on Defendant Takeda's and Eli Lilly's scheme depended in large part upon targeting third-party payors and insurers and convincing them to add Actos to their formularies. Actos was a much more expensive medication than older, available drugs that were often more effective, and more tolerable than Actos. The average monthly prescription cost for older diabetes drugs like metformin varied from $4 to $100. The cost for Actos varies from $87.03 and $388.57. The cost of Actos has an enormous impact on third-party payors, including Plaintiffs' Assignors.

18. Further, Defendant Takeda set out to persuade Plaintiffs' Assignors and the healthcare community, including third-party payors to favor Actos over alternative treatments that were cheaper, safer and/or more efficacious than Actos. As such, Plaintiffs' Assignors paid for Actos in quantities far exceeding its warranted use, and these payments were the direct result of Defendants Takeda's and Eli Lilly's fraudulent scheme.

19. This action arises given that Plaintiffs' Assignors paid for part or all of the purchase price of Actos, as a consequence of Defendants Takeda's and Eli Lilly's violation of the applicable state statutes set forth herein.

20. Plaintiffs seek compensatory damages as a result of their payment for Actos and the amounts by which Defendants Takeda and Eli Lilly were unjustly enriched, as well as punitive or statutory damages to the extent allowable under applicable state statutes.

II. THE PARTIES

a. Plaintiffs

21. Plaintiff, MSPRC, is a Delaware series limited liability company with its principal place of business located at: 2701 S. Le Jeune Road, 10th Floor, Coral Gables, Florida 33134. MSPRC's limited liability company agreement provides for the establishment of one or more designated series. All records of every series entity is maintained together with the assets of MSPRC.

22. Plaintiff, MSPRC, has established various designated series pursuant to Delaware law in order to maintain various claims recovery assignments separate from other company assets, and to account for and associate certain assets with certain particular series. All designated series form a part of MSPRC. Pursuant to MSPRC's limited liability operating agreement and applicable amendment(s), each designated series will be owned and controlled by MSPRC. MSPRC may receive assignments in the name of MSPRC and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event, MSPRC will maintain the right to sue on behalf of each series and pursue any and all rights, benefits, and causes of action arising from assignments to a series. Any claim or suit may be brought by MSPRC in its own name, or it may elect to bring suit in the name of its designated series.

23. Certain series of MSPRC have been irrevocably assigned any and all rights to recover payments made on behalf of their Assignors' health plan members and enrollees. These assignments authorize the series and, in turn, MSPRC, to pursue and enforce all legal rights of recovery and reimbursement for health care services and Medicare benefits.

24. Plaintiff's, MSPRC, limited liability operating agreement provides that any rights and benefits arising from assignments to its series shall belong to MSPRC.

25. Plaintiff, MSPA, is a limited liability company that is duly organized, validly existing, and in good standing under the laws of Florida, with its principal place of business in Miami-Dade County, Florida.

26. Plaintiff, Series PMPI, is a designated series of MAO-MSO Recovery II, LLC, whose principal place of business is located at 45 Legion Drive, Cresskill, New Jersey 07626.

b. Defendants

27. At all times relevant hereto, Defendant, TPA, is and was a corporation organized pursuant to the laws of New York, with its headquarters and principal place of business located at: One Takeda Parkway, Deerfield, Illinois 60015. At all relevant times herein, TPA was in the business of promoting, manufacturing, labeling, and distributing Actos.

28. At all times relevant hereto, Defendant, TPA USA, is and was a corporation organized pursuant to the laws of Delaware, with its headquarters and principal place of business located at: One Takeda Parkway, Deerfield, Illinois 60015. At all relevant times herein, TPA USA was in the business of promoting, manufacturing, labeling, and distributing Actos.

29. At all times relevant hereto, Defendant, TGRDC, is and was a corporation organized pursuant to the laws of Delaware, with its headquarters and principal place of business located at: One Takeda Parkway, Deerfield, Illinois 60015. At all relevant times herein, TGRDC was in the business of promoting, manufacturing, labeling, and distributing Actos.

30. At all times relevant hereto, Defendant, TPI, is and was a corporation organized pursuant to the laws of Delaware, with its headquarters and principal place of business located at: One Takeda Parkway, Deerfield, Illinois 60015. At all relevant times herein, TPI, was in the business of promoting, manufacturing, labeling, and distributing Actos.

31. At all times relevant hereto, Defendant, TPCL, is a foreign corporation organized under the laws of Japan with its principal place of business at 1-1, 5 Doshomachi, Chuo-Ku, Osaka, 540-8645, Japan. At all relevant times herein, TPCL, was in the business of promoting, manufacturing, labeling, and distributing Actos.

32. At all times relevant hereto, Defendant, Eli Lilly, is and was a corporation organized pursuant to the laws of Delaware, with its headquarters and principal place of business located at Lilly Corporate Center, Indianapolis, Indiana, 46285. At all relevant times herein, Eli Lilly, was in the business of promoting, manufacturing, labeling, and distributing Actos.

III. Standing

33. Plaintiffs have been assigned all legal rights of recovery and reimbursement for medical items and services provided by Assignors that administer Medicare benefits for Medicare beneficiaries under Medicare Part C and/or Medicare Part D; whether said rights arise from: (i) contractual agreements, such as participation and network agreements with capitation and risk sharing arrangements, and/or (ii) state and federal laws that provide for the reimbursement of payments made by the assignor health plans, including the right to recover claims for health care services on a fee-for-service basis.

34. The Assignors have assigned all rights, title, and interest to the recoverable claims, conferring standing to Plaintiffs to bring this lawsuit. These are all valid and binding contracts.

35. Assignors paid for the medical items and services related to the treatment of injuries caused by Actos that was prescribed to their Enrollees and ingested by their Enrollees across the United States.

36. Additionally, numerous Assignors paid for all or part of the cost of Actos prescribed and ingested by their Enrollees across the United States.

a. Plaintiff MSPRC's Standing

37. Certain series of MSPRC have been irrevocably assigned any and all rights to recover payments made on behalf of their Assignors' health plan members and enrollees. These assignments authorize the series and, in turn MSPRC through its operating agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and Medicare benefits.

38. The assignments to Plaintiffs, which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts. *See* **Exhibit A**.

b. Plaintiff MSPA's Standing

39. MSPA has been irrevocably assigned any and all rights to recover payments made on behalf of its Assignors' health plan members and enrollees. These assignments authorize MSPA to pursue and enforce all legal rights of recovery and reimbursement for health care services and Medicare benefits.

40. The assignments to Plaintiffs, which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts. *See* **Exhibit B**.

c. Plaintiff MAO-MSO's Standing

41. MAO-MSO has been irrevocably assigned any and all rights to recover payments made on behalf of its Assignors' health plan members and enrollees. These assignments authorize MAO-MSO to pursue and enforce all legal rights of recovery and reimbursement for health care services and Medicare benefits.

42. The assignments to Plaintiffs, which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts. *See* **Exhibit C**.

IV. JURISDICTION AND VENUE

43. This Court has federal question jurisdiction over this action under 28 U.S.C. § 1331.

44. This Court also has subject matter jurisdiction over this action under 28 U.S.C. § 1332(a) as there is complete diversity among Plaintiffs and Defendants Takeda and Eli Lilly, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

45. Defendants Takeda and Eli Lilly have significant contacts with this federal judicial district, such that they are subject to the personal jurisdiction of this Court, and at all relevant times hereto Defendants Takeda and Eli Lilly developed, manufactured, promoted, marketed, distributed, tested, warranted, and sold Actos in interstate commerce.

46. Additionally, pursuant to N.Y.C.P.L.R. 302, New York's Long-Arm Statute, Defendant Takeda is subject to the personal jurisdiction of this Court, given that Defendant Takeda transacts business within the state or contracts to supply goods or services within the state; committed a tortious act within the state; committed a tortious act causing injury to person or property within the state; regularly does or solicits business, engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered, in the states, and/or expects or should reasonably expect the act to have consequences in the state and derives substantial revenue from interstate or international commerce. Exercising personal jurisdiction of Defendant Takeda does not offend traditional notions of fair play and substantial justice.

47. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in this federal judicial district.

48. Pursuant to 28 U.S.C. § 1391(a) venue is proper in this district.

V. FACTUAL ALLEGATIONS

a. FDA Regulations for Marketing and Promotion in the United States

49. Pursuant to the Federal Food, Drug and Cosmetic Act ("FDCA"), new pharmaceutical drugs may not be marketed in the United States until the FDA determines that the drug is "safe for use" and effective for all "conditions prescribed, recommended, or suggested" on a drug's label. *See* 21 C.F.R. 99.103; *see also* 21 C.F.R. § 201.5.

50. The indications and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also approved by the FDA.

51. A manufacturer's statement that a drug is "effective" or "works" or "has been proven to . . ." is understood to mean that well-controlled clinical studies support the use. To make such a statement without such clinical trial proof is misleading. Further, failure to inform physicians that no placebo-controlled clinical trials support a representation of drug efficacy is a violation of a pharmaceutical company's obligation to disclose the necessary information. *See* 21 C.F.R. § 99.205.

52. In any other circumstance, a manufacturer cannot disseminate information regarding a drug to health care practitioners, pharmacy benefit managers, health insurance issuers, or federal and state government agencies unless such information is fair and balanced and the manufacturer meets the following conditions:

(a) The information concerns a drug that has been approved, licensed and cleared for marketing by the FDA;

(b) The information is in the form of an unabridged copy of a peer-reviewed scientific or medical journal article or reprint, or an unabridged reference publication that pertains to a clinical investigation involving the drug and that is considered scientifically sound by experts who are qualified to evaluate the product's safety or effectiveness;

(c) The information does not pose a significant risk to the public health;

(d) The information is not false or misleading; and

(e) The information is not derived from clinical research conducted by another manufacturer, unless permission is received from that manufacturer.

See, 21 C.F.R. § 201.6(a); *see also* 21 U.S.C. §§ 360aaa; 360aaa-1.

53. With regard to the second practice—manufacturer's involvement in CME programs—the FDA's examination of these practices led to the publication of an agency enforcement policy in 1997 entitled, "Guidance for Industry: industry-Supported Scientific and Educational Activities." 62 Fed. Reg. 64,074,64,093, 1997 WL 740420 (F.R.)(1997). This guidance document states that CME programs must be truly independent of the drug companies and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." *Id*.

54. Section 502(a) and 201(n) of the FDCA (21 U.S.C. §§ 352(a), 321(n)) require Defendants Takeda and Eli Lilly to fully and accurately disclose information in Defendants Takeda's and Eli Lilly's possession relating to the efficacy of Actos, as well as information relating to adverse events associated with Actos use, including but not limited to bladder cancer events. These disclosures must appear in the Actos Package Insert ("Actos PI"), other labeling, and promotional materials.

55. Sections 502(a) and 201(n) of the FDCA (21 U.S.C. §§ 352(a) and 321(n)) prohibit Defendants Takeda and Eli Lilly from claiming efficacy or minimizing risks of adverse events, and from making misleading claims that Actos is safer or more effective than other available medications.

56. Defendants Takeda and Eli Lilly violated Sections 502(a) and 201(n) of the FDCA (21 U.S.C. §§ 352(a) and 321(n)) by omitting information concerning risks and benefits from the Actos PI and other labeling, and by utilizing and/or distributing promotional materials that were false and misleading regarding Actos's efficacy and effectiveness.

57. Furthermore, Defendants Takeda and Eli Lilly minimized the risks of these serious adverse events, failed to advise consumers and physicians to monitor patients for these adverse events, and otherwise falsely claimed that Actos was safer and more efficacious than other medications available on the market. Thus, the information disseminated by Defendants Takeda and Eli Lilly was not fair and balanced.

b. The FDA's Approval and Defendant Eli Lilly's Involvement

58. Defendant Takeda submitted its New Drug Application ("NDA") for Actos on January 15, 1999, seeking an indication for the treatment of Type II diabetes. At the same time, Defendant Takeda began discussing a partnership with Defendant Eli Lilly, to aid in the marketing and selling of Actos once the FDA approved the drug. Defendant Eli Lilly, however, was concerned about why Upjohn had cancelled its prior partnership with Defendant Takeda. In a facsimile transmission from Japan to the United States, on January 21, 1999, Kunio Iwatani of Defendant Takeda informed Larry Ellingson of Eli Lilly that, although there were rumors about why Upjohn abandoned development of Actos, the FDA had never been told it was related to safety issues. The facsimile stated:

> Enclosed please find a copy of Upjohn's letter to US FDA dated January 7, 1994.
>
> > In the letter Upjohn said that in preliminary clinical evaluation in the United States. pioglitazone did not satisfy Upjohn's internal requirement for reduction blood glucose; therefore, the considerable programs required for development of pioglitazone are not in line with Upjohn's business needs. – They did not mention about safety of pioglitazone.
> >
> > . . .
> >
> > Although there may be rumors about the reasons of Upjohn's abandonment of pioglitazone development, specially from the viewpoints of safety issues, it might be advisable for us to keep saying that Upjohn's decision is based on the results of their internal

> business evaluation, and efficacy and safety of pioglitazone have been demonstrated clearly by Takeda.

59. Thus, Defendants Takeda and Eli Lilly agreed to "stick to their story" (a frequent theme in this fraudulent enterprise) about Upjohn's abandonment of Actos development. Defendant Eli Lilly knew that Defendant Takeda was not being truthful with the FDA about Upjohn's withdrawal and, in accord with their enterprise to sell Actos without properly warning about its risks, remained silent. It did not matter that the FDA was being misled about the actual reasons for Upjohn's decision or, for that matter, the existence of serious safety concerns regarding the use of Actos in humans.

60. Prior to entering into any agreement with Defendant Takeda, Defendant Eli Lilly prepared a PowerPoint slide deck discussing the major contract terms between the parties. On that slide deck, "bladder cancer" is listed below the heading "most significant adverse event risks for pioglitazone[.]" This document demonstrates that both Defendants Takeda and Eli Lilly knew of the potential risks of bladder cancer associated with Actos.

61. Notwithstanding, Defendants Takeda and Eli Lilly entered in a "Co-Promotion Agreement" to act as distributors and "co-promoters" of Actos in the United States once approved by the FDA. The co-promotion agreement provided for an elaborate governance structure, designed to give each company an equal say in running the joint venture. Defendants Takeda and Eli Lilly agreed to share in the profits and losses of marketing Actos. The agreement was to last for a period of seven years after the launch of Actos and, in addition, Defendant Eli Lilly was to be paid a residual "Co-Promotion" fee on sales of Actos in the U.S. for a period of time following the expiration of the term of the agreement.

62. Under the Co-Promotion Agreement, Defendant Eli Lilly agreed to a target of 800,000 primary details per year for Actos. Also, under the terms of the Co-Promotion Agreement,

Defendants Takeda and Eli Lilly agreed to undertake the promotion of Actos together, with each company's name and/or logos appearing with equal prominence on the product, sample packages, product label, and all promotion material. Hence, the Co-Promotion Agreement constituted a much broader agreement than other traditional marketing or advertising agreements.

63. In fact, Defendant Eli Lilly's role was not limited to detailing physicians. Rather, Defendant Eli Lilly was charged with the broader overall marketing and promotion of Actos, including activities not traditionally associated with marketing, including: overseeing customer medical services; participation in clinical studies; participation in regulatory issues; exchange of information related to Adverse Events; post-marketing surveillance; and *communication with the FDA regarding labeling issues*.

64. Defendant Eli Lilly was also charged with generating scientific information about Actos, which despite the appearance of independence, were designed to persuade doctors to prescribe Actos, and pharmacy and therapeutic ("P&T") committee members to place Actos on Plaintiffs' Assignors formularies. Defendant Eli Lilly also explicitly agreed to not use data from clinical studies that would negatively affect sales of Actos, which amounted to an agreement to hide from the public and the medical community results of clinical studies that showed problems with Actos.

65. The Co–Promotion Agreement also provided for a 3–year period following the end of the actual agreement during which Defendant Eli Lilly was, nonetheless, to be paid a fee based upon the sales of Actos during that residual period—in acknowledgement of and due to the anticipated success of Defendant Eli Lilly's marketing and promotion efforts: "In recognition that . . . Lilly's efforts . . . will be important in maximizing the commercial potential of Actos . . . and Actos will, in all probability, continue to be a commercial success even after Lilly is no longer

participating in the promotion . . . Takeda shall pay Lilly a residual co-promotion fee on sales of Actos in the territory (all United States) . . . for an additional three years following the expiration of the term of the agreement."

66. Defendant Eli Lilly played not a passive, but an active role acting in tandem with Defendant Takeda, in developing the strategy for responding to the FDA's requests (discussed below), and that Defendant Eli Lilly's communications about Actos were funneled to the highest executive levels in Japan. Specifically, communications from Defendant Eli Lilly went directly to Mr. Saito, Senior Director, Pharmaceutical Development Division, Strategic Development Department (Takeda Pharmaceutical Company), for transmission to Defendant Takeda's CEO. Defendant Takeda, also, communicated important information to Defendant Eli Lilly and kept Defendant Eli Lilly apprised as new information became available throughout the course of the development and marketing process and suggested nuanced language for use in at least one study.

67. Defendant Takeda kept Defendant Eli Lilly up to date on all issues relating to Actos and obtained Defendant Eli Lilly's consent not to disclose information about the safety risks associated with Actos to Defendant Eli Lilly distributors until receiving instructions to do so from Defendant Takeda. Defendant Eli Lilly also agreed with Defendant Takeda not to raise safety risks during a telephone conference call with physicians in 2003.

68. In Comprehensive Meeting Materials dated August 5, 2002, a section entitled "Responses to FDA," refers to a four-way conference call among Defendant Eli Lilly and several Defendant Takeda employees; the stated reason for the call was to "stress the importance of managing information" regarding the safety risks associated with Actos and to confirm the future communication routes.

69. On July 15, 1999, the FDA approved the Defendant Takeda's NDA. In the FDA's Pharmacology Review for Actos, the medical reviewer who examined the NDA took note of the bladder cancer risks in rats and the proposed Cohen hypothesis. The reviewer observed "[i]n reference to the bladder cancer tumors, although the proposed mechanism of mechanical irritation by calculi is plausible, there are not sufficient data to conclusively determine that this mechanism [sic] is wholly responsible for the bladder tumors observed in the male rats." Nonetheless, the reviewer grudgingly accepted Cohen's explanation because Actos had not shown a propensity to alter DNA information (genotoxicity). The reviewer concluded that the bladder cancer findings in the rat and mice studies were not sufficiently problematic to recommend rejecting approval.

70. Accordingly, Dr. Cohen, in collusion with Defendant Takeda and Eli Lilly, was able to deceive the FDA about the safety risks associated with Actos, by "explaining away" the bladder cancer risk observed in the rat studies with the Cohen hypothesis.

71. The conspiracy and collaboration to develop a sham explanation of the rat and mice bladder cancer data was done in furtherance of a group effort to obtain FDA approval for Actos and to market Actos as though it did not pose a risk of bladder cancer. Dr. Cohen was rewarded with payments from Defendant Takeda and the prestige of being an expert in the expanding OAD marketplace, and Defendants Takeda and Eli Lilly were rewarded with a "plausible" explanation of the alarming bladder cancer data.

c. Defendants Takeda and Eli Lilly Aggressively Promote Actos as Superior to Avandia

72. Once Actos was approved by the FDA, Defendants Takeda and Eli Lilly began to aggressively market Actos in the United States.

73. The approval of Actos occurred shortly after a competing OAD TZD, Avandia, was approved. Avandia was researched and developed by GlaxoSmithKline, Inc., and is in the same

class of OADs as Actos in that it increases insulin sensitivity through PPAR gamma activation. From the moment Actos entered the market, the two products battled head-to-head in the marketplace and this competition made the concealment of any safety risks all the more important.

74. Once Actos was introduced on the market, Defendants Takeda and Eli Lilly competed against Avandia by asserting that, unlike Avandia, Actos lowered LDL cholesterol levels and raised HDL cholesterol levels. Defendants Takeda and Eli Lilly claimed this because Actos was shown, in addition to activating PPAR gamma, to also activate PPAR alpha. Since PPAR alpha activation is associated with improving cholesterol profiles, Defendants Takeda and Eli Lilly used this fact to claim that Actos provided, in addition to improving insulin sensitivity, improved cholesterol benefits. Avandia, however, did not have comparable PPAR alpha activation.

75. The reduction of cholesterol risks in addition to controlling blood sugar operated as an "important hook" in convincing physicians of Actos' superiority over Avandia. In fact, in sales representative training materials, Defendants Takeda and Eli Lilly instructed sales representatives to promote Actos as superior to Avandia because Actos "has a small degree of PPAR [alpha] affinity and activity, while Avandia has been reported to have none."

76. In line with this marketing approach, on October 27, 2000, several scientists for Defendant Takeda published Activation of Human Peroxisome Proliferator-Activated Receptor (PPAR) Subtypes by Pioglitazone in Biochemical and Biophysical Research Communications medical journal. In this article, Defendant Takeda's scientists stated that Actos, in addition to being a PPAR gamma agonist, was also a weak PPAR alpha agonist, and that the scientists observed that Actos caused PPAR alpha activation.

d. Emerging Evidence about Dual PPAR Alpha/Gamma Agonists within FDA Prompts Bladder Cancer Concerns

77. On July 28, 2002, Defendant Takeda began receiving phone calls from the FDA alerting them of the bladder cancer risks associated with glitazars (a new class of OAD that activated both alpha and gamma PPARs). The development of those glitazars were discontinued due to those safety risks. Defendant Eli Lilly was immediately informed of this problem and was consulted about the appropriate strategy moving forward.

78. On July 31, 2002, Claire Thom, one of the primary Defendant Takeda executives in charge of Actos, sent an e-mail to various personnel at Takeda, relaying the substance of her conversations with the FDA. Thom's e-mail contained bullet points highlighting the concerns raised by the FDA, and explained:

> Underlying these issues is a fundamental belief by the agency that the 'Cohen hypothesis' for bladder tumors in the pioglitazone rat studies is not relevant. The agency is no longer satisfied that the tumor formation is a species-specific finding nor that the origin is related to calculi formation. FDA disclosed that they have received data from a dual PPAR agonist (the Novo Nordisk compound) in which bladder tumors were found (not gender or species specific) in the absence of calculi. Based on these data, FDA has drawn the conclusion that tumor formation must be the result of class pharmacology instead of mechanical origin (calculi irritation). The agency is also not convinced that our findings are isolated to the rat. They commented that our lack of findings in the mice, dog and monkey are unconvincing due to the limited duration of exposure and limited number of animals. In addition, FDA has further evidence from a bladder tumor promotion study in which pio was compared to another sponsor's compound and was shown to increase the formation of bladder tumors (have tumor promoting capabilities). Details on the design and results of this study could not be disclosed.
>
> We have been requested to respond to the FDA in writing within 3-4 weeks. We are currently pulling a detailed action plan together which we will share with you.

This information was also relayed to Defendant Eli Lilly's executives.

79. A summary of a conversation between Defendant Takeda's personnel and the FDA's Dr. Jeri El-Hage, dated August 13, 2002, stated that "Dr. El-Hage noted that in light of the fact that several compounds that are dual PPAR agonist have discontinued development due to transitional cell tumors in the bladder and kidneys of male and female rats and in male mice, the

Division [of the FDA] is becoming concerned." Dr. El-Hage expressed concern that PPAR gamma and PPAR alpha activation led to bladder cancer and believed this applied to Actos. Dr. El-Hage explained that these bladder tumors were not caused by the Cohen hypothesis because "in follow-up studies, there was no irritation or formation of calculi noted."

80. In the same conversation, Dr. El-Hage relayed the results of a recently completed "promoter" trial involving Actos. In that trial, rats were divided into three groups. The first group received Actos and a compound known to cause bladder tumors, *i.e.,* a cancer initiator. The second group received a glitazar (the compound under investigation) and the initiator. The third group was just given the initiator. The results indicated that 85% of the animals in the group receiving Actos developed tumors, and only 15% of the animals in the third group developed tumors. Dr. El-Hage explained that "[b]ased on these findings, and the fact that other dual PPAR agonist have discontinued from development, the Division does not feel that the general population is being adequately informed about the possible risk of dual PPARs."

81. Dr. El-Hage, on behalf of the FDA, stated she wanted the Actos label changed to "reflect the relatedness of tumor formation to mechanism (dual PPAR agonist) instead of the current language." Dr. El-Hage wanted Defendant Takeda to propose a method by which to monitor bladder toxicity in patients in long term Actos clinical trials. Dr. El-Hage also indicated the FDA's inclination to rescind testing Actos in children, which would have disallowed an additional six months of patent exclusivity.

82. In response to the FDA's concern over Actos and bladder cancer, Defendant Takeda executives converged in an "Actos FDA Response Meeting" from August 12-13, 2002. Approximately two dozen Defendant Takeda executives attended the meeting. During the meeting, Philip Collett, an executive with Defendant Takeda in Europe, outlined the strategy that Defendant

Takeda successfully used to fend off a similar inquiry by the European equivalent of the FDA. In his PowerPoint presentation, Collett boiled their strategy down to:

(a) Persistence.
–We stuck to Sam Cohen's hypothesis despite many challenges.

(b) Argued against clinical testing.

(c) Did not "turn over any stones"
–*e.g.*, Did not undertake database searches.

(d) Supported by experts at every opportunity.

83. The minutes of the meeting stated:

Main Points from Takeda Europe Experience

(a) Takeda Europe successfully employed the following strategy:

- Defended Cohen hypothesis, despite numerous challenges
- Stressed the "one sex, one species" argument
- Challenged authorities regarding implementing monitoring plan
- Offered to conduct a case control study post-approval

Highlights from PPAR Agonist Discussion

(b) The group extensively discussed many aspects of the PPAR mechanism and ultimately decided to not address mechanistic issues in the initial FDA response.

84. Ultimately, the purpose of this meetings was to resist any label changes (unless Avandia was required to do so as well), continue to assert the Cohen hypothesis, resist the monitoring of patients in clinical trials for bladder cancer, offer to conduct a case-control study, and to avoid discussing the PPAR mechanism with the FDA. *Instead of taking steps to ensure its product was safe for humans, Defendant Takeda chose to engage in a deliberate strategy of obfuscation— the strategy successfully used in Europe*.

85. Defendant Takeda communicated its strategy to Defendant Eli Lilly via electronic wires. Defendant Eli Lilly, in turn, instructed its sales force, also via electronic wires, to stop promoting Actos as a dual PPAR agonist and to start telling prescribers that Actos was a selective PPAR gamma agonist—a fact that Defendant Eli Lilly knew was false. On information and belief, Defendant Eli Lilly thereafter engaged in the wholesale destruction of documents linking Actos to PPAR alpha activation and made changes to its website in response to the FDA's 2002 inquiries. This was done in furtherance of the ongoing enterprise to conceal the safety risks associated with Actos. Defendant Eli Lilly was fully aware of the Defendant Takeda's position and knew that representing Actos as a selective PPAR gamma agonist to the FDA was false. Nonetheless, Defendant Eli Lilly contributed to the fraud by retooling its promotional efforts by instructing its sales force to pitch the new message.

86. Defendants Takeda's and Eli Lilly's strategy to avoid any bladder cancer warning worked. Defendant Takeda was able to convince the FDA that Actos was not a dual PPAR agonist, and that it was only an activator for PPAR gamma—not PPAR alpha. Defendant Takeda used numerous "experts" to support this claim and was able to avoid adding a bladder cancer warning to the label. One expert with whom Defendants Takeda and Eli Lilly worked closely to accomplish this was Dr. Charles Burant from the University of Michigan. Dr. Burant conducted experiments to help Defendants Takeda and Eli Lilly support the new regulatory message that Actos did not activate PPAR alpha. This strategy (of enlisting experts to spout false theories) was frequently used by Defendants Takeda and Eli Lilly. Indeed, that was how the Cohen hypothesis was created. Coordination of these fraudulent theories was perpetrated using the U.S. mail and electronic wires. Similarly, Defendants Takeda and Eli Lilly coordinated their conduct with Dr. Burant using the

U.S. mail and electronic wires, while relying on one another to effectuate a misunderstanding within the FDA about whether Actos causes PPAR alpha activation.

e. Marketing of Actos as Superior to Avandia Poses Problems

87. Defendant Takeda, however, had a problem. Defendants Takeda and Eli Lilly had continually marketed Actos as a PPAR alpha agonist to better compete against Avandia. Defendants Takeda and Eli Lilly claimed that Actos' PPAR alpha activation promoted better cholesterol profiles over Avandia, which only activated PPAR gamma. After the FDA's concern about dual PPAR agonists, however, Defendants Takeda and Eli Lilly realized the need to distance themselves from Actos' PPAR alpha activation properties.

88. For example, in November 2002, when Defendant Eli Lilly circulated a manuscript for a study linking Actos' lipid benefits to its PPAR alpha activation, Defendant Takeda's executive Claire Thom reacted in an e-mail and stated: "I think we should think 100 times before we make a deliberate reference to Actos PPAR alpha agonist activity as an explanation for lipid benefits." On November 9, 2002, Thom sent another e-mail and stated, "I believe we need to do more than 'discuss' it. I think we are talking about making a very high-level strategic decision . . . around whether we continue to deliberately point out the alpha activity of Actos."

89. Similarly, on December 4, 2002, the Defendant Takeda's marketing executive, Dan Orlando, wrote an e-mail to Dr. Burant. In the e-mail, Orlando expressed his interest in continuing the promotion of Actos as a dual PPAR agonist so as to offer a superior safety profile over Avandia. Orlando stated that he had "[l]aid out my plans to get to work on a 'mixed PPAR' promotional message with Rich and he claimed that you might have some hesitancy there. Bottom line, all heads (Claire and Rich) are looking to you for direction[.]" Dr. Burant instructed Orlando that any message regarding Actos being a dual PPAR agonist posed significant risk. He stated:

> I really think you need to consider the whole franchise. Basically, the FDA is thumping you with the thought that mixed agonists cause bladder cancer and we just spent the last 4 months fighting this and will likely be doing it in the future…The first step is to dissociate pio from the other compounds, *i.e.*, some sort of physical effect, but given the FDAs insistence that 'mixed agonists' are the bad guys, the first is to get away from them.
>
> [O]ne of the last items that was put to the FDA (please read the treatis[e] that was sent yesterday by Janet Haskins et al) is that IN THE RAT, there is no evidence of intrinsic ppar alpha activity….
>
> [T]he issue is pediatric indication, because if pediatric goes, I don't think that marketing the mixed agonist stuff will in any way make up for the loss in revenue from that hit, along with the potential losses from the 'cancer' stigmata that is surely to be used[.]

90. In essence, Dr. Burant advised Defendants Takeda and Eli Lilly that they needed to be careful in managing any dual PPAR agonist marketing because it could pose great financial risk.

91. Defendants Takeda and Eli Lilly persisted in downplaying the safety risks associated with Actos. In January 2003, as part of the "label negotiation strategy," Orlando advised that the decision was made that "conducting market research on possible label language around bladder cancer would risk public awareness…" Linking the animal trial results to humans was seen as having a negative impact on sales: "In Marketing's assessment any of the proposed changes which imply a clinical connection would have an impact on sales. Any clinical language would likely be used by GSK to differentiate Avandia on safety…"

92. On April 4, 2003, Thom announced to Dr. Kitazawa that the strategy to fend off the FDA, in conjunction with numerous experts like Dr. Burant, had worked—"The FDA has agreed to our proposal to remove the language 'The relationship of these findings in male rats to humans is unclear' with no other language to be added to the label."

93. The safety risks concerns, however, did not go away. In December of 2003, Defendant Takeda compiled and presented a PowerPoint entitled "Barriers to TZD Prescribing Qual Report." The report anticipated a future world in which Actos was associated with bladder cancer and how a warning about bladder cancer would affect sales. As part of the report, the Defendant Takeda surveyed doctors regarding a new OAD that also contained a bladder cancer warning. Doctors responded very negatively. For instance, one prescriber stated "Bladder tumors? That would change my thinking altogether. I would not be likely to use the product." Another stated "[i]f there is a risk of bladder tumors, I would definitely not use it." In sum, interest declined "greatly" in 75% of the surveyed physicians and interest declined "slightly" in the rest. This study and survey confirmed what Defendants Takeda and Eli Lilly already knew—any warning of bladder cancer for Actos would dramatically reduce prescriptions and sales. Accordingly, Defendants Takeda and Eli Lilly continued to make every effort to resist bladder cancer labeling, and further shield any knowledge of the safety issues from P&T committee members.

94. The issue of telling the FDA one thing (Actos is a selective PPAR gamma agonist only) versus Defendants Takeda's and Eli Lilly's marketing efforts (Actos' lipid benefits are related to its PPAR alpha activation) also continued to be a problem. In August 2004, Defendant Takeda's scientists, who were not aware of the ongoing enterprise, published a journal article indicating that Actos was a mixed PPAR gamma and PPAR alpha agonist. This article prompted an e-mail to be sent to various Defendant Takeda executives by Miyazaki Masahiro on September 21, 2004, asking for people to express what "regulatory impact" the article would have. In response, the Defendant Takeda's Europe Managing Director David Eckland circulated an email to Masahiro and other Defendant Takeda executives expressing serious concern with the publication of the article:

> Over the last 18 months or more…we have been vigorously defending Pioglitazone from consistent regulatory attack. Part of this has been based on the pharmacology of pioglitazone, which with your help we have defined as a pure gamma agonist at clinical concentrations. We have worked hard to produce a pharmacological hypothesis which allows the differentiation of Pioglitazone from [Avandia]…This recent paper…states repeatedly that pioglitazone has mixed gamma and alpha activity at clinical concentrations…I was very surprised to see this paper in print, without having had any preview, or advance notice of its submission or publication…
>
> The most severe impact could be that regulators will no longer believe us when we give explanations, which could lead to the suspension of pioglitazone from the market in Europe, and I am sure severe consequences in US market (especially as FDA have just included a s[t]atement in the US label to say that pio is a pure gamma agonist… Most likely, is that as a result of not believing us anymore, regulators will now assert that pioglitazone is a mixed alpha gamma agonist, and that the likely toxicological implications are severe. This will lead to changes in the data sheet…describing the probability that Pioglitazone may cause cancer in man. There may be severe restrictions on using pioglitazone (eg limit duration of use to 6 months), and further long term clinical trials will become extremely difficult to do [(]from a regulatory prospective). I am sure our marketing colleagues could tell you of the potential impact on sales of our drug.

95. Eckland was concerned that the publication would reveal that Defendants Takeda and Eli Lilly had deceived regulatory agencies in the United States, and of the impact that it could have on their ability to market Actos.

96. Rather than concede that Actos was a dual PPAR alpha/gamma agonist and announce to physicians and patients that there was a bladder cancer connection with Actos, Defendant Takeda executives worried about their credibility, the impact on sales, and how this study demonstrating that Defendants Takeda and Eli Lilly lied to the FDA was published without advance notice.

97. This was not an isolated concern—a few days later, another Defendant Takeda executive, Mick Roebel, echoed Dr. Eckland's e-mail, sending his own on September 30, 2004:

> As you know, during recent labeling negotiations with FDA re: non-clinical findings, [Takeda] successfully pushed back on the Agency to reiterate that Actos is a selective PPAR gamma agonist. FDA accepted our label wording ("Urinary

> tract tumors have been reported in rodents taking experimental drugs with dual PPAR alpha/gamma activity; however, Actos is a selective agonist for PPAR gamma"). This new publication calls this statement into question, and (since it is our publication), it could appear that we intentionally mislead the Agency. Could the Agency decide to revisit the label wording in light of this new publication?
>
> We have been devising a strategy to revisit the clinical hold for pediatric studies that we are currently under with Actos. It seems possible that companies with dual alpha/gamma compounds may find it more difficult to get FDA approval to do ped. studies. This new publication can only hurt us as we try to reinstitute ped. trials, and may adversely affect our ability to get 6 mo. additional exclusivity (pediatric exclusivity) for Actos if we're unable to pursue appropriate trials.
>
> re: suggestions - at other companies I've been at, a goal has been to tightly manage a product like Actos on a global basis, with research/development/commercial people all being on the "same page" and with a minimum of internal "surprises" arising. This can be difficult to do, but is key to protecting/opt[i]mizing the brand. I know we're trying to do this at Takeda also, and that over the past few years we're started to put global processes in place. However, as we all know, Actos is key to our short and (at least) medium term future, so we need to find a process to ensure that all pieces of the company that are dealing with Actos understand and support the product's profile/positioning, and that any new initiatives (preclinical or clinical studies, marketing approaches, etc) are consistent with this view.

98. Defendants Takeda and Eli Lilly showed no concerns about the safety risks associated with Actos and even proposed to continue their efforts to test Actos in children so as to obtain an extra six months of patent exclusivity. Capturing an extra six months of exclusive sales was worth billions of dollars to Defendants Takeda and Eli Lilly.

f. The PROactive and KPNC Data Raises Additional Alarm about the Safety Risks Associated with Actos

99. As part of Defendants Takeda's and Eli Lilly's marketing efforts to promote Actos, a clinical trial was conducted to determine whether Actos offered superior cardiovascular benefits over other drugs, i.e., Avandia. Another reason for conducting this clinical trial was to ascertain whether an increased risk of bladder cancer exists, and Defendant Takeda agreed to inform the FDA in an expedited fashion of new cases of bladder cancer discovered during the study; to

unblind those study subjects and, for any such subject taking pioglitazone, remove him or her from the clinical trial.

100. During the course of the clinical trial, 19 people developed bladder cancer: 14 were in the group taking Actos, while 5 of them were in the control group. The PROactive study found that the group taking Actos had a statistically significant increase in bladder cancer than those in the controlled group.

101. Despite Defendant Takeda's earlier promise to unblind the subjects who developed bladder cancer, Defendant Takeda failed to do so.

102. On March 10, 2004, Defendant Takeda justified its decision not to provide this information to the FDA by claiming that Takeda Europe Research & Development, Ltd. Preferred not to break the study blind, given its obligation to European regulators. However, Takeda Europe Research & Development, Ltd. had not existed as a separate corporate entity for over two months.

103. It wasn't until 2005 that Defendant Takeda published the study. *See* Dormandy J.A., et al., *Secondary Prevention of Macrovascular Events in Patients with Type 2 Diabetes in the PROactive Study (PROspective PioglitAzone Clinical Trial In MacroVascular Events): a Randomised Controlled Trial*, Lancet, 266:1279-1286 (2005) (the "Dormandy paper").

104. Around this same time, Defendant Takeda performed a statistical analysis of the FDA AERS database. That analysis showed a signal for bladder cancer when comparing Actos to all drugs in the AERS database; however, Defendant Takeda edited the table so as to omit this statistical analysis from the final reports reported by Defendant Takeda to the FDA, and thereby included only non-significant signals of Actos when compared to other OADs. Furthermore, Defendant Takeda failed to reveal to the FDA the result of the October 2005 Disproportionality

Analysis showing a signal of excess bladder cancer among Actos patients, despite in the face of the FDA's request, in May 2006, for "any recent data you may be aware of."

105. Also around this same time, Defendant Takeda had also finished its first preliminary analysis of data collected from the Kaiser Permanente Northern California ("KPNC") database, monitoring the incidences of bladder cancer in Actos users. Defendant Takeda agreed to a request by the FDA to conduct an epidemiological study concerning the association between Actos and bladder cancer using the KPNC database. The protocol called for interim analyses and a nested case control to account for confounding factors.

106. In 2005, Defendant Takeda was required to submit the bladder cancer data from the PROactive Study and initial KMPC analysis to the FDA and European regulatory authorities. Both studies contained data showing an association between Actos and bladder cancer. Philip Collett sent an e-mail to Defendant Takeda executives regarding the upcoming submission on August 5, 2005. This e-mail prompted a response from Wada Yasuhiko in Japan, which stated:

> As the reports on malignancy to the authorities are of critical importance for Actos, you are requested to pay very very careful attention to this matter by all means. To ensure that the interpretation is right to avoid unnecessary arguments against the safety of Actos, you better consult with the outside experts like epidemiologists in prior to your submission to EMEA/FDA
>
> . . .
>
> [W]e need to know the following scenario in terms of responses given by authorities you should predict when you submit the reports to EMEA and FDA from regulatory perspective.
>
> 1) Most likely scenario, 2) Best case scenario and 3) Worst case scenario[.]

107. In response, Mick Roebel, the Vice President of Regulatory Affairs in the United States, outlined the various best and worst-case scenarios:

> [T]he bladder cancer issue has died down in the US over the last several months. We continue to provide expedited Safety Reports for cases of bladder cancer to the

Agency, as agreed in Feb. 2003. For PROactive specifically, we informed FDA in Mar. '04 of a number of cases of bladder cancer from the trial but told them we did not want to break the study blind at that time in order to maintain study integrity. We assured the Agency that the DSMB had approved the continuation of the study. FDA did not question us on this.

Best Case Scenario
As in the EU, it's not unlikely that the Metabolism and Endocrinology Div. at FDA will request some sort of labeling change. Best case is that this happens subsequent to our PROactive US submission and data review, and includes relatively benign wording around bladder cancer findings from the study along with "benefits" wording if trial is positive.

Worst Case Scenario
It seems pretty unlikely in the US that the FDA would try to remove the drug from the market given the equivocal safety data seen. However, the overall evaluation is, of course, a benefit/risk proposition and if the PROactive "benefit" turns out to be worse than neutral (decrease mortality, other?) this could change. A more likely "worst case scenario" could be for the Agency to ask for an immediate label change incorporating bladder cancer findings, possibly some sort of a "Dear Healthcare Provider" letter to be sent, and posting of pioglitazone on the new "Drug Watch" portion of the FDA Web page. This "Drug Watch" list, accessible to the public, is meant to identify drugs for which FDA is actively evaluating safety signals during a period of uncertainty while FDA and the Sponsor evaluate new, significant safety information. The situation would first be discussed by the new FDA Drug Safety Oversight Board prior to any posting; the company may or may note be involved in! these discussions. If pioglitazone were to be posted, I would expect the media to pick this up. The Agency could also ask us to put together some sort of Risk Management plan for the product to minimize any possible bladder cancer risks associated with pioglitazone (ways to identify populations most at risk, only treat populations most benefiting from product, etc.)

Most Likely Scenario
Depends on overall results of PROactive, but "most likely" is expected to be more like "best case" than like "worst case". Depending on how FDA views our pharmacovigilance plan[.]

108. Defendant Takeda executive, Kiyoshi Kitazawa, responded stating that "As you understand very well, Actos is the most important product for Takeda and therefore we need to manage this issue very carefully and successfully not to cause any damage for this product globally."

109. Once again, Defendant Eli Lilly was informed about this ongoing bladder cancer issue and how an FDA warning would impact its ongoing efforts to market and sell Actos in the United States in furtherance of the enterprise. And, once again, Defendant Eli Lilly's concerns were to protect Actos and hide the bladder cancer risk from, patients, prescribers, TPPs, and the FDA.

110. When the PROactive study was published in the Lancet in 2005, it did not reveal the statistically significant increase in the risk of bladder cancer. Dr. John Dormandy, the lead author of the paper, conspired with Defendants Takeda and Eli Lilly to misrepresent the data. Specifically, the PROactive paper published in 2005 reported that there were 14 (0.5%) cases of bladder neoplasms in the Actos group and 6 (0.2%) in the controlled group. In truth, one of the neoplasms in the controlled group had been deemed to be a benign tumor and, per the study's protocol, should not have been counted. This change in the data from 6 to 5, however, would have rendered a statistically significant difference between the Actos and controlled groups. Defendants Takeda and Eli Lilly coordinated their conduct with Dr. Dormandy using U.S. Mail and electronic wires and relied on one another to effectuate a misunderstanding about the PROactive trial within the medical community. This was done to facilitate the overall enterprise of concealing any safety risks associated with Actos.

111. This deception was unveiled by independent scientists, Drs. Hillaire-Buys, Faillie, and Montastruc. These researchers recalculated the risk ratio after removing the benign tumor from the controlled group and concluded that there was a statistically significant 2.83 times greater risk of bladder cancer amongst the PROactive participants randomized to Actos. In the October 29, 2011 Lancet, these researchers explained that "…this result shows a significant relation between pioglitazone and bladder cancer, which has not been presented in the PROactive study reports…

This finding, associated with the preclinical and clinical finding reported on the FDA website in 2004 (PPAR agonists were claimed to be multi-species, multistrain, multisex and multisite carcinogens), could have led to an alert ***5 years sooner***. With this in mind, pioglitazone prescription could have been restricted, and monitoring of patients strengthened." (emphasis added).

112. Dr. Dormandy's miscounting is reflected in the label change in 2006, stated:

> In two 3-year studies in which pioglitazone was compared to placebo or glyburide, there were 16/3656 (0.44%) reports of bladder cancer in patients taking pioglitazone compared to 5/3679 (0.14%) in patients not taking pioglitazone. After excluding patients in whom exposure to study drug was less than one year at the time of diagnosis of bladder cancer, there were six (0.16%) cases on pioglitazone and two (0.05%) on placebo.

113. This language, however, although properly reflecting the five reports of bladder cancer in the controlled group, did not clarify the previous inaccurate publication and/or correctly reflect the statistical significance of the bladder cancer risk for the patients exposed to Actos. Instead, it omitted the statistical comparison without reference to the previously published incorrect number and included language downplaying the connection, in addition to placing the information in the section of labeling related to animal findings, thereby suggesting it was not a human problem.

g. The FDA's Response to the PROactive and KPNC Data

114. In the latter part of 2005 and through July 2006, shortly after the submission of the PROacive and preliminary KPNC data to the FDA, Defendant Takeda sought approval for a drug combining Actos with another OAD, glimeprimide. The FDA's medical reviewer was Dr. Robert Misbin, who had been involved with the earlier evaluations of the link between Actos and bladder cancer in 2002. In this 2006 Medical Review, Dr. Misbin summarized the bladder cancer findings in the animal trials and two post-approval human trials:

> Bladder cancers were found in mice in preapproval studies of pioglitazone and in most, if not all, mixed PPAR agonists. In addition, Merck has found that both its PPAR agonist and pioglitazone promoted growth of bladder cancers in the presence of the tumor initiator BBN.
>
> . . .
>
> The following is a summary of new findings related to bladder cancer from phase 4 clinical trials lasting two years or longer.
>
> . . .
>
> Taking all cases, there were 17/3656 (0.47%) reports of bladder cancers in patients taking pioglitazone compared to 5/3679 (0.14%) in patients not taking pioglitazone. The one case of benign bladder tumor in a placebo patient in PROactive has been excluded. Of the three cases of bladder cancer in study 506, one was a recurrence. If we exclude this case, and restrict the analysis to new diagnoses, there are 16 cases on pioglitazone and 5 on placebo/glyburide. The odds ratio from the stratified analysis performed by FDA is 3.24 (95% CI limits: 1.2, 9.9), p=0.02. Excluding diagnoses within one year of starting the test drug, there were two cases bladder cancer on placebo and six on pioglitazone. All of these were from PROactive.

115. Dr. Misbin's analysis indicated that there was a statistically significant risk ratio of 3.24 for Actos in causing bladder cancer. Elsewhere in his 2006 report, Dr. Misbin explained how Defendant Takeda, used the Cohen hypothesis to obfuscate a link to bladder cancer:

> Bladder tumors had been found in mice in preapproval studies of pioglitazone. Because there were no similar findings with troglitazeon or rosigiltazone (Avandia), FDA initially accepted the explanation offered by Takeda that the tumors were due to the presence of bladder calculi in the pioglitazone studies. It later became clear that most, if not all, mixed PPAT* agonists were associated with bladder tumors in animal toxicology studies. In addition, Merck found that both its PPAR agonist [redacted] and pioglitazone promoted growth of bladder tumors in the presence of a tumor initiator, BBN (butyl-nitrosbutyl nitrosamine). These issues were discussed with Takeda in a telecom of July 31, 2002.

116. Dr. Misbin further explained that, in 2004, the FDA proposed amending the Actos label to include bladder cancer language, but that:

> Takeda declined to go along with this recommendation. In an attempt to come up with "physician-friendly" language that would be acceptable to Takeda, the following proposal for wording was faxed to Takeda on November 24, 2004:

> Urinary tract tumors have been reported in rodents taking experimental drugs with dual PP AR alpha/gamma activity.
>
> Initially, Takeda declined to go along with this wording. However, in a submission dated April 9, 2004, they proposed the following:
>
> Urinary tract tumors have been reported in rodents taking experimental drugs with dual PPAR alpha/gamma activity; however ACTOS is a selective agonist for PPAR gamma.
>
> The phrase "ACTOS is a selective agonist for PPAR gamma" was already in the label, so no new claims were being made.

117. Dr. Misbin noted that Defendant Takeda's resistance to adding bladder cancer warnings as well as their insistence that Actos is a selective gamma agonist only, attempting to distinguish Actos from glitazars and their link to bladder cancer. Dr. Misbin stated that Actos is more likely a dual agonist since Actos raised HDL and lowered LDL, a property of alpha agonism. He suggested that the selectivity language be removed from the Actos label.

118. Despite Dr. Misbin's recommendations, Defendant Takeda continued to not update the Actos warning label and continued to market Actos without warning patients and prescribers of the known bladder cancer risks. Indeed, Defendants Takeda and Eli Lilly were receiving an average of more than 180 cancer reports each year (1,813 over ten years) from spontaneous sources, but Defendants Takeda and Eli Lilly never included these cancer reports in the label, and never issued a Dear Doctor Letter to warn the medical community of the risk of developing cancer while taking Actos.

119. In September 2006, Defendant Eli Lilly ended its partnership with Defendant Takeda although Defendant Eli Lilly continued to receive royalty payments through 2009.

120. In 2009, pursuant to Defendant Takeda's 2003 agreement with the FDA to conduct periodic reviews of the KPNC data, a new report was submitted to the FDA. The results of the analysis were alarming. The data showed a statistically significant increase in the risk of bladder

cancer for use of Actos longer than 24 months (risk ratio of 4.8) and for patients who took a cumulative dose over 28,000 mg (risk ratio of 4.6). These numbers were adjusted for possible confounding factors such as smoking history, high risk occupations, and urinary tract infections.

121. The FDA reacted to the interim KPNC report by announcing, on September 17, 2010, that it was conducting an on-going safety review of Actos for the potential increased risk of bladder cancer.

h. Whistleblower Federal False Claim Act Lawsuit Alleges Defendant Takeda Concealed Congestive Heart Failure Adverse Effects Associated with Actos

122. Approximately three (3) months before the FDA announced its investigation, a federal false claim act case was filed by a whistleblower, Dr. Helen Ge. *See U.S. ex rel. Helen Ge v. Takeda Pharmaceutical Co.,* 10-cv-11043(D.C. Mass. 2011). Dr. Ge was a Contract Physician with Defendant Takeda between September 2008 and January 2010 and was responsible for reviewing adverse events associated with various Defendant Takeda products, including Actos. During her time working for Defendant Takeda, Dr. Ge reviewed multiple adverse event reports involving Actos and bladder cancer. Dr. G concluded that Actos was causally related to bladder cancer. Defendant Takeda's management, however, pressured Dr. Ge to change her assessment and find, contrary to her medical opinion, that Actos was "unrelated" to the adverse bladder cancer event. Dr. Ge then initiated an investigation and discovered that Defendant Takeda had been systematically underreporting the incidence of bladder cancer in adverse even reports. Dr. Ge filed her complaint under seal on June 18, 2010 in the United District Court for the District of Massachusetts.

123. In the instant action, Dr. Ge alleged that Defendant Takeda failed to properly identify or report all of the Actos related congestive heart failure ("CHF") adverse events to the FDA, despite the fact that the FDA classified CHF as a serious adverse event by placing a Black

Box CHF warning on the Actos' package insert in 2007. Instead, Defendant Takeda instructed medical reviewers not to classify non-hospitalized or non-fatal CHF cases as serious from late 2007 to January 2010. According to Dr. Ge's complaint, it is estimated that Defendant Takeda failed to report several hundred CHF adverse events as serious during this time frame.

124. Dr. Ge also alleged that "Takeda's motivation to fraudulently report and under-report the serious adverse events was driven by an economic desire to falsely enhance Actos' safety profile and to increase sales." *U.S. ex rel. Helen Ge v. Takeda Pharmaceutical Co.*, 10-cv-11043 at 4. Dr. Ge alleged that Dr. Maria Paris, Vice President of Takeda's Pharmacovigilance Department, informed her and other Defendant Takeda employees that "as a company, reporting adverse events is one thing, but we must make sure that the company has to be profitable first." *Id.*

125. Dr. Ge's complaint further described in many instances, that Defendant Takeda "improperly instructed" its medical reviewers to "change their professional opinion regarding adverse event classifications and assessments." *Id*. at 4-5. When Dr. Ge protested, her contract was summarily terminated.

i. Suspension of Actos in Europe and its Impact

126. On June 9, 2011, the European Medicines Agent announced that it was informed by the French Medicines Agency of its decision to suspend the use of pioglitazone-containing medicines (Actos, Competact) in France while awaiting the outcome of the ongoing European review. The decision by French regulators was based upon a retrospective cohort study in France using the French National Health Insurance Plan, which demonstrated a statistically significant increase in the risk for bladder cancer in males exposed to Actos for more than one (1) year. The French cohort included 1.5 million patients with diabetes who were followed for four (4) years (2006-2009).

127. On June 10, 2011, Reuters published that Germany had joined France in suspending the use of Actos after Germany's Federal Institute for Drugs and Medical Devises ("BfArM") reviewed the results of the French study. BfArM recommended that doctors should not put new patients on pioglitazone.

128. On June 15, 2011, the FDA issued this safety announcement, linking long term use of Actos to bladder cancer, based on the KNPC data, as well as the French study that led to Actos being suspended in France and Germany:

> The U.S. Food and Drug Administration (FDA) is informing the public that use of the diabetes medication Actos (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer. Information about this risk will be added to the *Warnings and Precautions* section of the label for pioglitazone-containing medicines. The patient Medication Guide for these medicines will also be revised to include information on the risk of bladder cancer.
>
> This safety information is based on FDA's review of data from a planned five-year interim analysis of an ongoing, ten-year epidemiological study, described in FDA's September 2010 ongoing safety review and in the Data Summary below. The five-year results showed that although there was no overall increased risk of bladder cancer with pioglitazone use, an increased risk of bladder cancer was noted among patients with the longest exposure to pioglitazone, and in those exposed to the highest cumulative dose of pioglitazone.

129. After the FDA had conducted its own internal investigation, and after France and Germany had effectively removed Actos from the market, Defendant Takeda finally changed the Actos warning label to warn of a bladder cancer risk—a risk it knew or should have known about before the drug was ever approved by the FDA.

130. The American Diabetic Association held its annual convention towards the end of June 2011. In preparation for the marketing opportunities at the convention, Defendant Takeda's marketing department prepared a PowerPoint presentation for their marketing personnel entitled "Strengthen Your Core." Defendant Takeda's sales representatives were given a verbatim pitch to use to temper prescribers' concerns over bladder cancer. However, Defendant Takeda's personnel

were instructed to "wait for [prescribers] to ask the question before using the verbatim. If no questions/concerns, do not discuss bladder cancer and sell, sell, sell!" Once again, the emphasis was on avoiding conveying bladder cancer information.

131. In September 2011, Defendant Takeda provided additional KPNC data pursuant to the FDA's request. It showed, again, a statistically significant increase in the risk of bladder cancer for use of Actos longer than twenty-four (24) months (risk ratio of 4.4) and for patients who took a cumulative dose over 28,000 mg (risk ratio of 4.6). It also showed a statistically significant risk ratio of 9.4 for consumers of between 10,501 and 28,000 mg of Actos.

132. As Defendant Takeda's marketing department and executives predicted, once the bladder cancer warning was added to the Actos label in 2011, Actos sales collapsed. According to expert analyses, the sales of Actos dropped shortly after the FDA's alert in 2010, and then again when the FDA issued the bladder cancer warning in 2011 (before Actos went generic). The precipitous drop, accounting for a decline of approximately 80% of sales, indicated that, because prescribers and patients were unaware of the bladder cancer risk from 1999 through 2011, Defendants Takeda and Eli Lilly were able to sell many prescriptions for Actos that they otherwise would not have been able to absent the fraud. Essentially, if Defendant Takeda had issued bladder cancer warnings from the beginning, the enhanced warnings would have caused reduction of approximately 80% of sales.

133. In August 2012, Actos went generic, spawning the proliferation of less expensive generic competitors and ending the profitability of the enterprise.

134. In 2016 the FDA conducted an updated review of the Actos bladder cancer risk and after reviewing all up-to-date data, concluded, once again, that the drug "may be linked to an increased risk of bladder cancer." FDA Drug Safety Communication, Updated FDA Review

Concludes that Use of Type II Diabetes Medicine Pioglitazone May be Linked to an Increased Risk of Bladder Cancer (Dec. 12, 2016) at 1.

135. The current label for Actos states, on the first page: "Bladder Cancer: May increase the risk of bladder cancer." This statement is neither false nor misleading.

136. Plaintiffs allege that this statement should have been included on the Actos labeling and marketing materials since the drug entered the market in 1999.

j. Spoliation: Defendants Takeda and Eli Lilly Destroy Documents and Conceal Fraudulent Conduct

137. Through July 2002, Defendants Takeda and Eli Lilly openly promoted the lipid benefits of Actos over Avandia, pointing to the fact that Actos induced PPAR-alpha activation. On July 19, 2002, a product liability suit was filed against Takeda regarding Actos. As a result of this action, Defendant Takeda's legal department circulated a litigation hold to preserve all documents concerning Actos. A litigation hold directs company personnel to not destroy documents related to some litigation despite the company's document retention policy authorizing destruction of documents when employees leave or after a certain amount of time has elapsed.

138. According to the 2002 Litigation Hold:

> A motion has been filed to add Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. as defendants in a lawsuit. The plaintiff in this lawsuit seeks damage for personal injury and wrongful death allegedly resulting from the use of certain prescription drugs, including Actos.
>
> To be able to respond to discovery requests from the plaintiff, if that becomes necessary, we must take steps to preserve any documents that may be called for in this lawsuit.
>
> Until further notice, you are instructed to preserve any and all documents and electronic data which discusses, mentions, or relates to Actos. This means do not destroy, delete, throw away or otherwise discard any such documents or electronic data. This includes correspondence, records, and data, contained in your paper and electronic files, regardless of form and include email correspondence and attachments and electronic data.

> Action Steps:
>
> Please interpret this directive in its broadest sense to prevent the deletion or destruction of any recorded information and data relating in any way to Actos.
>
> Please take steps immediately to preserve such documents and data within your department.
>
> Please distribute his memo to members of your group and advise them of the importance of following these instructions.

(emphasis in original). This litigation hold was distributed across the entire company.

139. Defendant Takeda's 2002 hold was renewed on a number of occasions through 2011, including in 2003, 2006, 2007, 2008, and 2011. Specifically, an additional hold was imposed in December 2010 related to a document demand issued by the Texas Attorney General's office regarding Defendant Takeda's Adverse Event Reporting. At first, during discovery in the federal Actos bladder cancer multi-district litigation ("MDL") proceedings coordinated in Lafayette, Louisiana, Defendant Takeda told the MDL Plaintiffs Steering Committee that the unavailability of certain employees' files was the result of the normal document retention policy – there was no litigation hold in place barring routine document destruction until February 2011.

140. Despite the alleged February 2011 hold, Defendant Takeda destroyed their executive Mr. Miyazaki's Actos-related computer records, e-mails and files in the spring and summer of 2011.

141. Then Defendant Takeda asserted that their statement that there was no hold until February 2011 was a mistake—it was really August 2011, so destroying Mr. Miyazaki's files was okay. Eventually, Defendant Takeda's in-house counsel, Stacey Calahan, conceded that Defendant Takeda destroyed a wealth of Actos-related documents between 2002 and 2011 inconsistent with the litigation holds that had been in place since 2002.

142. Despite actual knowledge of Defendant Takeda's duty to preserve evidence, files of at least forty-six witnesses across multiple continents were destroyed, deleted, or otherwise lost. Examples of the custodians whose files were destroyed in whole or in part, include a President of Takeda Global Research and Development (John Yates); Managing Director (Kiyoshi Kitizawa, David Eckland); Vice President, Pharmaceutical Research Division (Masaomi Miyamoto, Takashi Nonoyama); Director, Pharmaceutical Development Division (Mikihikio Obayashi); Senior Director, Pharmaceutical Development Division (Katsuhisa Saito); Representative Director, Chairman of the Board (Kunio Takeda), Senior Vice President – Sales (Harry (Dean) Hart); Senior Manager – Product Safety (Doug Joseph), Director Epidemiology, Pharmacovigilance (Annette Beiderbeck); and Vice President- Regulatory Affairs (Philip Collett), to name a few. At least 38 of the 46 custodians whose files were destroyed were deleted after 2002 when Defendant Takeda already had in place the 2002 Litigation Hold. Moreover, the files of these custodians were destroyed in a manner that contravened the retention policies that governed the destruction of documents during the relevant time.

143. In addition, Defendants Takeda and Eli Lilly destroyed promotional materials indicating that Actos was a PPAR alpha agonist, a part of their decision to abandon the PPAR alpha agonist promotional slant.

144. The manner and speed with which the files were destroyed, the characteristics of the custodians who were targeted (many senior executives involved in critical regulatory, safety, and science positions), and the widespread nature of the destruction indicate that the destruction was done in bad faith.

145. In January 2014, United States District Judge Rebecca F. Doherty, the judge overseeing the MDL proceedings, issued a spoliation order finding that Defendant Takeda had

destroyed or failed to preserve 46 custodial files of personnel who worked on Actos and in particular the Actos bladder cancer issue. The files of many senior executives who worked on Actos were destroyed, including Dr. Kitazawa's files. The importance of some of the documents that were destroyed was established by documents obtained from Upjohn which contained correspondence to, from and concerning Dr. Kitazawa.

146. During the first MDL bellwether trial, deposition testimony from Dr. Ge was played regarding her work in Defendant Takeda's pharmacovigilance department. In October of 2009, Dr. Ge reviewed a report of a bladder cancer adverse event report from a study and deemed it related to Actos. When Takeda Japan queried the basis for her determination, she was directed by her United States superiors not to put her explanation in writing because it would be discoverable in litigation:

> Q. And in your response, you did not respond to even one of the questions asked by Japan; isn't that true?
>
> A. No. Because Michelle Peralta send me e-mail asking me to stop response. They don't want to establish any e-mail document traffic for future lawsuit. That's their purpose. That was Michelle Peralta came to my office and told me, hey, you got to stop responses to Japan. All these e-mail will be subject to subpoena.

This demonstrated that Defendant Takeda was fully aware of the litigation effect of writing emails and that Dr. Ge's research regarding the relationship between Actos and bladder cancer would be subject to litigation discovery.

147. At the conclusion of the MDL's trial's testimony, Judge Doherty insured the jury that Defendant Takeda had an obligation to retain Actos-related documents as of July 2002, but key Defendant Takeda executives' files related to Actos were destroyed and that spoliation had occurred. This conduct in destroying documents in violation of the Federal Rules of Civil Procedure, federal law, and Court orders, was done in furtherance of Takeda and the enterprise's

efforts to conceal any correlation between Actos and bladder cancer and the numerous ways in which Takeda and the enterprise misled the FDA, patients, prescribers, and TPPs about the significant risk of Actos causing bladder cancer.

VI. STATUTE OF LIMITATION TOLLING ALLEGATIONS

a. Defendants Takeda and Eli Lilly Face Thousands of Actos Lawsuits

148. Beginning in 2011, a multitude of lawsuits were filed throughout the country against Defendants Takeda and Eli Lilly for their failure to disclose the safety risks associated with Actos.

149. According to the first Motion to Transfer filed with the Judicial Panel on Multidistrict Litigation ("JPML") as of August 2011, there were at least eleven (11) actions pending in eight (8) district courts alleging injury from the use of Actos and seeking recovery from the Defendants Takeda and Eli Lilly.

150. In December of 2011, plaintiffs in a Southern District of Illinois action moved for coordinated or consolidated pretrial proceedings of eleven (11) actions pending in eight (8) districts.

151. On the basis of the papers filed and the hearing session held in the Southern District of Illinois, the Court found that eleven actions, all which were filed in July 2011 or later, involved common questions of fact, and that centralization in the Western District of Louisiana would serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. In each of these actions, the plaintiffs alleged that individuals who used Actos, faced an increased risk of developing bladder cancer, and that the defendants concealed their knowledge of this risk, and failed to provide adequate warnings to consumers and the health care community.

152. On December 29, 2011, the Court ordered that pursuant to 28 U.S.C. § 1407, the actions listed in above be transferred to the Western District of Louisiana, Lafayette Division, and, with the consent of that court, assigned to the Honorable Rebecca F. Doherty, for coordinated or consolidated pretrial proceedings in an MDL. *See In re: Actos Products Liab. Litig.*, 840 F. Supp. 2d 1356, 1357 (U.S. Jud. Pan. Mult. Lit. 2011) (hereinafter "MDL No. 2299").

153. As the MDL progressed, there were approximately 4,500 Actos-related lawsuits filed in (or removed to) federal district courts throughout the nation, that were transferred into (or filed in) these proceedings. Another approximately 6,500 were filed in (and remained pending in) state court systems throughout the country.

154. Among the complaints filed in the MDL, plaintiffs alleged claims such as: (1) strict liability; (2) negligent failure to warn; (3) negligent design; (4) negligence; (5) negligence per se; (6) negligent misrepresentation; (7) breach of implied warranty of merchantability; (9) breach of implied warranty of fitness for a particular purpose; (9) breach of express warranty; (10) fraud; and (11) violation of consumer protection laws.

155. In addition to the cases filed in federal courts that were consolidated in the MDL, approximately an equal number of cases were filed in state courts throughout the United States. Particularly large number of cases were filed in Illinois and California.

156. In response to a Motion to Transfer and Consolidate, the Illinois Supreme Court found that the approximately 4,000 Actos cases filed in Illinois state court would be complex and would share common issues, and recommended consolidation before one court for coordinated pretrial proceedings.

157. Similarly, the Los Angeles Superior Court conducted a hearing on a Petition for Coordination of the Actos cases filed in California. As a result of that hearing, the court found the

cases were complex and shared several common issues, and recommended consolidation before the Los Angeles Superior Court.

158. On January 27, 2014, jury selection began in the first, and what ultimately would become the only, bellwether trail conducted in these proceedings.

159. On April 28, 2015, Defendants Takeda and Eli Lilly entered into a Master Settlement Agreement ("MSA") that ultimately resulted in the global settlement of approximately 11,000 claims for $2.4 billion.

160. Although the MSA, itself, did not settle any claims outright, it created a complete Settlement Program whereby all aspects of all the individual claims and claimants, who could provide sufficient documentation of a history of Actos usage and a proper diagnosis of bladder cancer, would be eligible to apply to receive compensation, and would agree to dismiss any pending Actos related suits they might have against the defendants if their claim was accepted.

161. Additionally, numerous class action lawsuits were filed against Defendants Takeda and Eli Lilly. These class actions are delineated below:

b. Class Action Tolling

162. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling and class action tolling.

163. Despite diligent investigation by Plaintiffs into the cause of their injuries, including consultations with Plaintiffs' medical providers, the nature of Plaintiffs' injuries and damages, and their relationship with Actos was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims.

164. Plaintiffs' claims are tolled by the applicable statutes of limitations tolling provisions, as held by the Supreme Court of the United States in *American Pipe & Construction Co. v. Utah*, 414 U.S. 538 (1974).

165. The accrual and running of any applicable statute of limitations has been tolled since April 18, 2012 until April 26, 2018, and was then tolled again from May 8, 2018, until November 6, 2018, pursuant to *American Pipe*.

***Gary Bernor et al. v. Takeda Pharmaceuticals, Inc., and Eli Lilly & Company and DOES 1-100*, Case No. 12-cv-04856**

166. On April 18, 2012, plaintiffs Gary Bernor, William Jr. Buntin, Rogelio Sanchez, and Jadine Surrett filed a putative class action Complaint in the Superior Court of the State of California, County of Los Angeles against Defendants Takeda and Eli Lilly for the safety risks associated with Actos, and alleged the following causes of action: (1) violation of the California Consumers Legal Remedies Act; (2) violation of the California Unfair Competition law; (3) violation of the California False Advertising law; and (4) unjust enrichment.

167. The proposed class was defined as:

> All consumers who have been prescribed and purchased or paid, in part or all, of the purchase price other than for resale of the prescription drug Actos in California since July 1999.

168. Plaintiffs fall within the class definition, as their Assignors are TPPs that paid some or the entire purchase price of Actos in the state of California since July 1999.

169. On June 4, 2012, the class action was properly removed to the United States District Court for the Central District of California pursuant to the Class Action Fairness Act of 2005 ("CAFA"), 28 U.S.C. § 1332(d).

170. On July 9, 2012, pursuant to an order of the JPML, the case was transferred to the United States District Court for the Western District of Louisiana for inclusion in the Actos Product Liability Multidistrict Litigation, Case No.: 6:11-mc-2299 (W.D.L.A.).

171. In 2014, Defendants Takeda and Eli Lilly reached a settlement agreement in MDL No. 2299, which created a global settlement program for all eligible Actos personal injury claims. Each of the named plaintiffs in the action participated in the settlement, dismissed their personal injury claims, and released all claims related to Actos against Defendants Takeda and Eli Lilly, including the claims alleged in their action.

172. On December 18, 2017, Defendant Takeda filed a Motion to Dismiss and argued that the Court did not have subject matter jurisdiction over the action, as there was no longer a case or controversy since plaintiffs settled their personal injury claims and released all other claims, they had against Defendants Takeda and Eli Lilly relating to Actos. Subsequently, Defendant Eli Lilly filed a Joinder in Defendant Takeda's Motion to Dismiss.

173. On January 25, 2018, the Court granted the Defendants Takeda's and Eli Lilly's Motion to Dismiss, and dismissed the Complaint without leave to amend and with prejudice.

***Painters and Allied Traders District Council 82 Health Care Fund v. Takeda Pharmaceutical Co. Ltd.,* Case No. 14-cv-02359**

174. On July 23, 2014, Painters and Allied Trades District Council 82 Health Care Fund filed a putative class action Complaint in the United States District Court for the Western District of Louisiana against Defendants Takeda and Eli Lilly for the safety risks associated with Actos and alleged the following causes of action: (1) violations of 18 U.S.C. §§ 1962(c); (2) violations of 18 U.S.C. §§ 1962(d); (3) violations of Cal. Civ. Code §§1750, et seq.; (4) violations of Cal. Bus. Prof. Code §§ 17200, et seq.; (5) violations of Cal. Civ. Code §§ 17500, et seq.; (6) violations of Mo. Rev. Stat. §§ 407.010, et seq.; (7) violations of N.J.S.A. §§ 56:8-1, et seq.; (8) violations

of Fla. Stat. §§ 501.201, et seq.; (9) violations of Minn. Stat. §325F.69; (10) violations of Minn. Stat. § 325D.13; and (11) violations of Mass. Gen Laws Ch. 93A, §§1, et seq. *See Painters and Allied Trades District Council 82 Health Care Fund et. al. v. Takeda Pharmaceutical Co., Ltd. et. al.,* Case No. 17-cv-07223.

175. The proposed classes were defined as:

National Racketeer Influenced and Corrupt Organizations Act ("RICO") Class:

All consumers and entities in the United States of America and its territories, who paid or incurred costs for the drug Actos, for purposes other than resale, between 1999, *i.e.*, when the drug was approved, and the present. Excluded from the RICO Class are employees of Takeda, including its officers or directors, the Court to which this case is assigned, and those consumers who are presently seeking a personal injury claim arising out of their use of Actos.

California Consumer Class:

All consumers and entities in the State of California, who paid or incurred costs for the drug Actos, for purposes other than resale, between 1999, *i.e.*, when the drug was approved, and the present. Excluded from the California Consumer Class are employees of Takeda, including its officers or directors, the Court to which this case is assigned, and those consumers who are presently seeking a personal injury claim arising out of their use of Actos.

Missouri Consumer Class:

All consumers and entities in the State of Missouri, who paid or incurred costs for the drug Actos, for purposes other than resale, between 1999, *i.e.*, when the drug was approved, and the present. Excluded from the Missouri Consumer Class are employees of Takeda, including its officers or directors, the Court to which this case is assigned, and those consumers who are presently seeking a personal injury claim arising out of their use of Actos.

New Jersey Consumer Class:

All consumers and entities in the State of New Jersey, who paid or incurred costs for the drug Actos, for purposes other than resale, between 1999, *i.e.*, when the drug was approved, and the present. Excluded from the New Jersey Consumer Class are employees of Takeda, including its officers or directors, the Court to which this case is assigned, and those consumers who are presently seeking a personal injury claim arising out of their use of Actos.

Florida Consumer Class:

> All consumers and entities in the State of Florida, who paid or incurred costs for the drug Actos, for purposes other than resale, between 1999, *i.e.*, when the drug was approved, and the present. Excluded from the Florida Consumer Class are employees of Takeda, including its officers or directors, the Court to which this case is assigned, and those consumers who are presently seeking a personal injury claim arising out of their use of Actos.

Massachusetts Consumer Class:

> All consumers and entities in the Commonwealth of Massachusetts, who paid or incurred costs for the drug Actos, for purposes other than resale, between 1999, *i.e.*, when the drug was approved, and the present. Excluded from the Massachusetts Consumer Class are employees of Takeda, including its officers or directors, the Court to which this case is assigned, and those consumers who are presently seeking a personal injury claim arising out of their use of Actos.

176. Plaintiffs fall within the class definition, as their Assignors are TPPs that paid some or the entire purchase price of Actos in the United States.

177. On September 26, 2017, pursuant to an order of the Court, the case was transferred to the United States District Court for the Central District of California. *See Painters and Allied Trades District Council 82 Health Care Fund et. al. v. Takeda Pharmaceutical Co., Ltd. et. al.,* Case No. 17-cv-07223.

178. On April 3, 2018, the Court dismissed plaintiffs' Missouri, New Jersey, Florida, and Massachusetts claims with prejudice and plaintiffs' California and Minnesota claims without prejudice.

179. On April 26, 2018, the Court dismissed plaintiffs' Second Amended Complaint with prejudice and entered a final judgment against the plaintiffs.

***Frank Fernandez v. Takeda Pharmaceuticals America, Inc., and Eli Lilly & Co., et al.,* Case No. 18-cv-01142**

180. On May 8, 2018, Frank Fernandez filed a putative class action Complaint in the United States District Court for the Eastern District of California against Defendants Takeda and

Eli Lilly for the safety risks associated with Actos and alleged the following causes of action: (1) violations of Cal. Civ. Code §§1750, et seq.; (2) violations of Cal. Bus. Prof. Code §§ 17200, et seq.; (3) violations of Cal. Bus. Prof. Code §§ 17500, et seq.; and (4) unjust enrichment. *See Frank Fernandez v. Takeda Pharmaceuticals America, Inc., and Eli Lilly & Co.*, Case No. 18-cv-01142.

181. The proposed class was defined as:

> All consumers and entities in the State of California, who paid or incurred costs for the drug Actos, for purposes other than resale, between 1999, *i.e.,* when the drug was approved, and the present. Excluded from the California Consumer Class are employees of Takeda, including its officers or directors, the Court too which this case is assigned, and those consumers who are presently seeking a personal injury claim arising out of their use of Actos.

182. Plaintiffs fall within the class definition, as their Assignors are TPPs that paid some or the entire purchase price of Actos in the state of California.

183. On June 28, 2018, Defendant Takeda Pharmaceuticals America, Inc., filed a Motion to Dismiss. Subsequently, Defendant Eli Lilly and Company joined.

184. On November 6, 2018, the parties stipulated to the dismissal of the Complaint in its entirety with prejudice.

c. Discovery Rule Tolling

185. Plaintiffs and their Assignors had no way of knowing about Defendants Takeda's and Eli Lilly's scheme and deception regarding the safety risks associated with Actos, specifically as to bladder cancer, CHF, and other cardiovascular adverse events.

186. Within the time period of any applicable statutes of limitation, Plaintiffs and their Assignors could not have discovered through the exercise of reasonable diligence, that Defendants Takeda and Eli Lilly were concealing the conduct complained of herein and misrepresenting the nature of the safety risks associated with Actos.

187. Plaintiffs and their Assignors did not discover and did not know of facts that would have caused a reasonable person to suspect that Defendants Takeda and Eli Lilly were engaged in the overall scheme to conceal the safety risks associated with Actos. For these reasons, all applicable statutes of limitations are tolled by operation of the discovery rule with respect to claims concerning the Defendants Takeda's and Eli Lilly's wrongful actions.

d. Fraudulent Concealment Tolling

188. Any applicable statutes of limitations was tolled due to the concealment and denial of material facts known by Defendants Takeda and Eli Lilly when they had a duty to disclose those facts. Defendants Takeda and Eli Lilly kept Plaintiffs and their Assignors ignorant of vital information essential to the pursuit of these claims, without any fault or lack of diligence of Plaintiffs and their Assignors, for the purpose of obtaining delay in filing a complaint. Defendants Takeda's and Eli Lilly's fraudulent concealment resulted in such delay. Plaintiffs and their Assignors could not reasonably have discovered these claims until shortly before the filing of this Complaint.

189. Defendants Takeda and Eli Lilly were under a continuing duty to disclose the true character, quality, and nature of Actos, but instead concealed such vital information. As a result, Defendants Takeda and Eli Lilly are estopped from relying on any statute of limitations defense.

VII. Injury to Plaintiffs' Assignors

190. Defendants Takeda's and Eli Lilly's deceptive and misleading marketing scheme increased the number of prescriptions of Actos writing and filled. Because Defendants Takeda and Eli Lilly withheld material information about the true safety and efficacy of Actos, the prescribing physicians did not have the knowledge necessary to make informed decisions regarding Actos prescriptions. Plaintiffs' Assignors, unaware of Defendants Takeda's and Eli Lilly's scheme, paid

for these prescriptions. Although more effective, safer, and less expensive alternatives are available, Defendants Takeda's and Eli Lilly's promotion and marketing of Actos's safety and effectiveness has been highly successful, resulting in Defendants Takeda and Eli Lilly receiving billions of dollars in profits, representing ill-gotten gains to which Defendants Takeda and Eli Lilly were not entitled.

191. Plaintiffs' Assignors bear the ultimate responsibility of paying for their Actos prescriptions.

192. Pharmacy Benefit Managers ("PBM(s)") prepare a "formulary," which is a list of the drugs that are approved for coverage by their TPP clients, such as Plaintiffs' Assignors. Each Assignors' PBM directs formulary development teams, comprised of pharmacists who develop clinical reviews of drug classes, those clinical reviews are then incorporated into materials that the Plaintiffs' Assignors ultimately review. These reviews present all of the clinical information available about a drug class, including package inserts, and drug compendia. For a drug to be listed on the formulary, it must be assessed by the PBM P & T Committee for clinical *safety*, efficacy, and cost effectiveness. Further, where a PBM finds that a drug has an advantage over competing drugs, for example if one competing drug is marketed as dual PPAR antagonists versus a non-dual PPAR antagonist, that drug is given a preferred status on its formulary.

193. The level of preference on the formulary corresponds with the amount that a plan participant must contribute as a co-payment when purchasing a drug the higher the preference, the lower the co-payment, the more likely that the drug will be purchased by a prescription plan's beneficiary in lieu of a cheaper more cost effective alternative, and vice versa. As such, the higher a drug's preference on the formulary, the more likely it is for a physician to prescribe that drug.

This system is well known to pharmaceutical manufacturers, including Defendants Takeda and Eli Lilly.

194. Due to the large number of drugs purchased through TPPs, it is vital to a drug manufacturer's economic interests to have its product listed on as many formularies as possible.

195. By directly and falsely promoting Actos as safe and effective for Type II diabetes and training its sales forces and representatives to avoid alerting the FDA to its activities and to dismiss any safety concerns raised by physicians, Defendants Takeda and Eli Lilly influenced PBMs to place Actos on their formularies and higher in preference on those formularies.

196. Defendants Takeda and Eli Lilly falsely promoted Actos as safe and effective directly to PBMs in order to get Actos placed on or placed more favorably that its competitor drugs on the PBM formularies.

197. Patients, physicians, PBMs, pharmacy and therapeutic ("P&T") committee members, and TPPs relied on Defendants Takeda's and Eli Lilly's misrepresentations of Actos's safety. Physicians relied on Defendants Takeda's and Eli Lilly's safety in prescribing the drug for their patients. Patients relied on Defendants Takeda's and Eli Lilly's misrepresentations of Actos's safety in purchasing the drug. PBMs and P&T committees relied on Defendants Takeda's and Eli Lilly's misrepresentations regarding Actos's safety when approving and/or placing Actos on formularies. TPPs relied on Defendants Takeda's and Eli Lilly's misrepresentations regarding Actos's safety in reimbursing and/or paying for prescriptions of Actos for their Enrollees.

198. Therefore, Defendants Takeda's and Eli Lilly's failure to adequately inform consumers, TPPs and those in the medical community that the use of Actos dangerously increases the risk of bladder cancer, CHF, and other adverse cardiovascular effects, and its false and misleading promotion of Actos's efficacy over competing less expensive OADs, caused patients

and TPPs to pay for Actos, which is neither safer nor more effective than other less expensive OADs.

199. But for Defendants Takeda's and Eli Lilly's actions, TPPs would not have paid for Actos but would instead have paid for safer, equally efficacious drugs like metformin and/or sulfonylureas. Attached hereto as Exhibit D[7] is a non-exhaustive list of instances wherein Plaintiffs' Assignors paid for Actos. Plaintiffs' Assignors provided payment for their Enrollees' prescribed Actos throughout the United States, including in the state of New York.

VIII. Causes of Action

First Cause of Action
Violation of 18 U.S.C. § 1962(c) – RICO: Actos Promotion Enterprise

200. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

201. Defendants Takeda and Eli Lilly are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise, the Actos Promotion Enterprise, through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

202. The Actos Promotion Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendants Takeda and Eli Lilly, including their employees, agents and external consultants like Dr. Cohen, Dr. Burant, and Dr. Dormandy, and others as yet unknown consultants, marketing firms and distribution agents employed by Defendants Takeda and Eli Lilly to promote Actos. All entities are persons within the meaning of 18 U.S.C. § 1961(3) and acted to

[7] In Exhibit D, MSP MRD ID is the unique internal patient code, which is an internal number used in place of an individual's name; source NDC codes, or product names are included, NDC codes are unique codes for pharmaceuticals that delineate the labeler, the drug, and the dosage; product name is the name of the pharmaceutical; MSP DOS is the date of service; the value is how much Plaintiffs' Assignors paid for Actos; National Provider Identification ("NPI") number is the address of the pharmaceutical provider.

enable Defendants Takeda and Eli Lilly to fraudulently market Actos as scientifically proven as safe and effective. The Actos Promotion Enterprise is an organization that functioned as an ongoing organization and continuing unit. The Actos Promotion Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. Each of these entities, including Defendants Takeda and Eli Lilly, are a "person" distinct from the Actos Promotion Enterprise.

203. Defendants Takeda and Eli Lilly, in concert with other participants in the Actos Promotion Enterprise, created and maintained systematic links for a common purpose – to aid in marketing Actos as safe for its intended uses, while suppressing evidence to the contrary and concealing the drug's risk of causing bladder cancer, CHF, and other adverse cardiovascular effects, thereby and improperly inducing physicians to prescribe Actos. Each of the enterprise participants received substantial revenue from the fraudulent scheme to promote Actos as safe and effective for its intended uses. Such revenue was exponentially greater than it would have been if Actos was marketed appropriately and the true safety risks of Actos had been disclosed. All enterprise participants were aware of Defendants Takeda's and Eli Lilly's control over the activities of the Actos Promotion Enterprise in promoting Actos. Furthermore, each portion of the enterprise benefited from the existence of the other parts.

204. The Actos Promotion Enterprise engaged in and affected interstate commerce, because inter alia, it marketed, promoted, sold, or provided Actos to thousands of individuals and entities throughout the United States. The Actos transported in interstate commerce, however, was misbranded, in violation of 21 U.S.C. § 352 because the label contained misleading representations about the safety risks associated with Actos.

205. Defendants Takeda and Eli Lilly exerted control over the Actos Promotion Enterprise and management of the affairs of the Actos Promotion Enterprise.

206. Defendants Takeda and Eli Lilly conducted and participated in the affairs of the Actos Promotion Enterprise through patterns of racketeering activity, including acts indictable under 18 U.S.C. §§ 1341 (mail fraud); 1343 (wire fraud); 1512 (tampering with witnesses); and 1952 (use of interstate facilities to conduct unlawful activity).

207. Defendants Takeda's and Eli Lilly's fraudulent scheme consisted of, inter alia: deliberately misrepresenting the safety of Actos so that Plaintiffs' Assignors paid for this drug to treat symptoms for which it was not scientifically proven to be safe and effective and actively concealing and causing others to conceal, information about the safety of Actos.

208. Defendants Takeda's and Eli Lilly's use of the mail and wires to perpetuate its fraud involved thousands of communications, including, but not limited to:

(a) Communications with and among the Actos Promotion Enterprise participants that misrepresented the safety and risks of Actos amongst themselves and others;

(b) Communications with Plaintiffs' Assignors or their agents, inducing payments for Actos by misrepresenting the safety and risks of Actos;

(c) Receiving the proceeds in the course of and resulting from Defendants Takeda's and Eli Lilly's improper scheme;

(d) Transmittal and receipt of monies from Plaintiffs' Assignors or their agents; and

(e) Transmittal and receipt of payments in exchange for, directly or indirectly activities in furtherance of the Actos Promotion Enterprise.

209. At all times during the fraudulent scheme, Defendants Takeda's and Eli Lilly's and the enterprise participants had a legal and ethical obligation of candor to and honest dealing with public and private TPPs, physicians, and the medical community.

210. The conduct of the Actos Promotion Enterprise described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendants Takeda's and Eli

Lilly's decision and activity in connection with the Actos Promotion Enterprise to routinely conduct their transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. 1961(5).

211. Plaintiffs' Assignors have been injured in their property by reason of these violations in that Plaintiffs' Assignors paid hundreds of millions of dollars for Actos and the costs associated with the adverse effects experienced by Enrollees that they would not have paid had Defendants Takeda and Eli Lilly not engaged in this pattern of racketeering activity.

212. The injuries to Plaintiffs' Assignors were directly and proximately caused by Defendants Takeda's and Eli Lilly's racketeering activity.

213. Patients, physicians, PBMs, P&T committee members, and TPPs, including Plaintiffs' Assignors, directly relied on the racketeering activities of Defendants Takeda's and Eli Lilly's and the Actos Promotion Enterprise. Plaintiffs Assignors, directly and indirectly, relied on the representations as to the efficacy and safety of Actos as promoted by Defendants Takeda and Eli Lilly. Because Defendants Takeda and Eli Lilly controlled all knowledge of the tests upon which the claims of Actos's efficacy and safety were based, Plaintiffs' Assignors were obligated to rely on Defendants Takeda's and Eli Lilly's representations about Actos. Further, Defendants Takeda and Eli Lilly perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about Actos.

214. By virtue of these violations of 18 U.S.C., § 1962(c), Defendants Takeda and Eli Lilly are liable to Plaintiffs' for three times the damages sustained, plus the costs of this suit, including reasonable attorneys' fees.

215. By reason of the foregoing, and as a direct and proximate result of Defendants Takeda's and Eli Lilly's fraudulent misrepresentations, Plaintiffs' Assignors have suffered

damages. Plaintiffs are entitled to compensatory damages, punitive damages, costs and reasonable attorneys' fees.

216. By reason of the foregoing, Plaintiffs' Assignors have been damaged against Defendants Takeda and Eli Lilly in a sum that exceeds the jurisdiction of all lower courts.

Second Cause of Action

Violation of 18 U.S.C. § 1962(d) – RICO Conspiracy

217. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

218. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section."

219. Defendants Takeda and Eli Lilly have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Actos Promotion Enterprise described previously through a pattern of racketeering activity. Defendants Takeda and Eli Lilly conspired with, inter alia, publicists, sales representatives, medical professionals, academics and other intermediaries to promote Actos and suppress information about the safety risks associated with Actos.

220. Defendants Takeda's and Eli Lilly's co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiffs' Assignors of property.

221. The nature of the above-described actions of Defendants Takeda's and Eli Lilly's co-conspirator's acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d)

violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

222. As a direct and proximate result of Defendants Takeda's and Eli Lilly's overt and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiffs' Assignors have been and are continuing to be injured in their property as set forth more fully above.

223. Defendants Takeda and Eli Lilly sought to and have engaged in the commission of overt acts, including the following unlawful racketeering predicate acts:

(a) Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;

(b) Multiple instances of mail fraud violation of 18 U.S.C. §§ 1341 and 1346;

(c) Multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and

(d) Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

224. Plaintiffs' Assignors have been injured in their property by reason of these violations in that Plaintiffs' Assignors have paid hundreds of millions of dollars for Actos and the costs associated with the adverse effects experienced by Enrollees that they would not have paid had Defendants Takeda and Eli Lilly not conspired to violate 18 U.S.C. § 1962(c).

225. Injuries suffered by Plaintiffs' Assignors were directly and proximately caused by Defendants Takeda's and Eli Lilly's racketeering activity as described above.

226. Patients, physicians, PBMs, P&T committee members, and TPPs, including Plaintiffs' Assignors, directly relied on the racketeering activities of Defendants Takeda and Eli Lilly and the Actos Promotion Enterprise. Plaintiffs' Assignors, both directly and indirectly, relied

on the representations as to the efficacy and safety of Actos as promoted by Defendants Takeda and Eli Lilly. Because Defendants Takeda and Eli Lilly controlled all knowledge of the tests upon which the claims of Actos's efficacy and safety were based, Plaintiffs Assignors were obligated to rely on Defendants Takeda's and Eli Lilly's representations about Actos. Further, Defendants Takeda and Eli Lilly perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about Actos.

227. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants Takeda and Eli Lilly are liable to Plaintiffs for three times the damages Plaintiffs' Assignors have sustained, plus the cost of this suit, including reasonable attorneys' fees.

228. By reason of the foregoing, and as a direct and proximate result of Defendants Takeda's and Eli Lilly's fraudulent misrepresentations, Plaintiffs' Assignors suffered damages. Plaintiffs are entitled to compensatory damages, punitive damages, costs and reasonable attorneys' fees.

229. By reason of the foregoing, Plaintiffs' Assignors have been damaged as against Defendants Takeda and Eli Lilly in a sum that exceeds the jurisdiction of all lower courts.

Third Cause of Action
Violations of State Consumer Protection and Unfair and Deceptive Acts or Practices Statutes

230. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

a. Connecticut Unfair Trade Practices Act Conn. Gen. Stat. § 42-110a, *et seq.*

231. Plaintiffs' Assignors and Defendants Takeda and Eli Lilly are "persons" within the meaning of the Connecticut Unfair Trade Practices Act ("Connecticut UTPA").

232. Defendants Takeda and Eli Lilly provided Actos in trade and commerce. Defendants Takeda's and Eli Lilly's challenged conduct occurred in "trade" or "commerce" within the meaning of Conn. Gen. Stat. § 42-110a(4).

233. Defendants Takeda's and Eli Lilly's conduct, as described herein, constitutes both "unfair" and "deceptive" acts in violation of the Connecticut UTPA in that Defendants Takeda's and Eli Lilly's actions:

(a) offends public policy as it has been established by statutes, the common law, or otherwise—whether, in other words, it is within at least the penumbra of some common law, statutory, or other established concept of unfairness;

(b) are immoral, unethical, oppressive, or unscrupulous; or

(c) cause substantial injury to consumers.

234. Defendants Takeda and Eli Lilly engaged in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce in violation of the Connecticut UTPA.

235. As a direct and proximate result of Defendants Takeda's and Eli Lilly's statutory violations, Plaintiffs' Assignors paid for Enrollees' prescriptions of Actos, and the costs associated with the adverse effects experienced by Enrollees, which proximately caused Plaintiffs' Assignors injury.

236. Plaintiffs are entitled to recover their actual damages, punitive damages, and attorneys' fees pursuant to Conn. Gen. Stat. § 42-110g.

237. Plaintiffs also seek an order enjoining Defendants Takeda and Eli Lilly from engaging in unfair, unlawful, and/or deceptive practices and any other just and proper relief available under Conn. Gen. Stat. § 42-110g.

b. Georgia Fair Business Practices Act of 1975 Ga. Code Ann. § 10-1-390, *et seq.*

238. Plaintiffs' Assignors are "consumers" under the Georgia Fair Business Practices Act of 1975 ("GFBPA").

239. Defendants Takeda and Eli Lilly provided Actos in trade and commerce. Defendants Takeda's and Eli Lilly's challenged conduct occurred in "trade" or "commerce" within the meaning of GFBPA.

240. Defendants Takeda's and Eli Lilly's conduct, as described herein, constitutes "deceptive" and "unfair" acts or practices in violation of the GFBPA.

241. Despite knowing the true nature of their products and practices for years, Defendants Takeda and Eli Lilly intentionally and knowingly omitted and misrepresented material facts regarding their unfair and deceptive practices, as described herein, with the intent to mislead regulators, and consumers including, Plaintiffs' Assignors, and continued to engage in unfair and deceptive practices in violation of the GFBP. Plaintiffs' Assignors relief on the omissions and misrepresentations, as described herein.

242. Defendants Takeda's and Eli Lilly's unfair, unconscionable and deceptive acts or practices, as described herein, occurred in Georgia, and throughout the United States and its territories.

243. As a direct and proximate result of Defendants Takeda's and Eli Lilly's statutory violations, Plaintiffs' Assignors paid for Enrollees' prescriptions of Actos and the costs associated with the adverse effects experienced by Enrollees which proximately caused Plaintiffs' Assignors injury.

244. Pursuant to the GFBP, Plaintiffs are entitled to recover their actual damages, attorneys' fees, an order enjoining Defendants Takeda's and Eli Lilly's unfair and/or deceptive acts or practices.

245. Additionally, due to Defendants Takeda's and Eli Lilly's intentional, willful and egregious conduct and violation of the GFBP, as described herein, Plaintiffs are entitled to recover exemplary and treble damages.

c. Indiana Deceptive Consumer Sales Act Ind. Code § 24-5-0.5-1, *et seq.*

246. Plaintiffs' Assignors and Defendants Takeda and Eli Lilly are "persons" as defined by the Indiana Deceptive Consumer Sales Act ("Indiana DCSA").

247. Defendants Takeda and Eli Lilly are also "suppliers" within the meaning of Ind. Code § 24-5-0.5-2(a)(3).

248. Plaintiffs' Assignors' payments for the Actos are "consumer transactions" within the meaning of Ind. Code § 24-5-0.5-2(a)(3).

249. Defendants' conduct, as described herein, constitutes "deceptive" and "unfair" acts in violation of the Indiana DCSA.

250. Despite knowing the true nature of their products and practices for years, Defendants Takeda and Eli Lilly intentionally and knowingly omitted and misrepresented material facts regarding their unfair and deceptive practices, as described herein, with the intent to mislead regulators, and Plaintiffs' Assignors, and continued to engage in unfair and deceptive practices in violation of the Indiana DCSA.

251. Defendants Takeda's and Eli Lilly's unfair, unconscionable and deceptive acts or practices, as described herein, occurred in Indiana, and throughout the United States and its territories.

252. As a direct and proximate result of Defendants Takeda's and Eli Lilly's statutory violations, Plaintiffs' Assignors paid for Enrollees' prescriptions of Actos and the costs associated

with the adverse effects experienced by Enrollees which proximately caused Plaintiffs' Assignors injury.

253. Pursuant to Ind. Code § 24-5-0.5-4, Plaintiffs seek monetary relief against Defendants Takeda and Eli Lilly measured as the greater of (a) actual damages in an amount to be determined at trial and (b) statutory damages in the amount of $500 for each Plaintiff, including treble damages up to $1000 for Defendants Takeda's and Eli Lilly's willfully deceptive acts.

254. Plaintiffs also seek an order enjoining Defendants Takeda's and Eli Lilly's unfair and/or deceptive acts or practices, attorneys' fees, and any other just and proper relief available under Indiana law.

d. Michigan Consumer Protection Act Mich. Comp. Laws § 445.902, *et seq.*

255. Plaintiffs' Assignors are "person[s]" within the meaning of the Mich. Comp. Laws § 445.902(1)(d).

256. Defendants Takeda and Eli Lilly are "persons" engaged in "trade or commerce" within the meaning of the Mich. Comp. Laws § 445.902(1)(d) and (g).

257. Defendants Takeda's and Eli Lilly's conduct, as described herein, constitutes both "deceptive" and "unfair" acts or practices in violation of the Michigan CPA.

258. Defendants Takeda's and Eli Lilly's unfair, unconscionable and deceptive acts or practices, as described herein, occurred in Michigan, and throughout the United States and its territories.

259. As a direct and proximate result of Defendants Takeda's and Eli Lilly's statutory violations, Plaintiffs' Assignors paid for Enrollees' prescriptions of Actos and the costs associated with the adverse effects experienced by Enrollees which proximately caused Plaintiffs' Assignors injury.

260. Plaintiffs seek: injunctive relief against Defendants Takeda and Eli Lilly to prevent continuing unfair and deceptive acts; monetary relief against each Defendant Takeda and Eli Lilly measured as the greater of (a) actual damages in an amount to be determined at trial and (b) statutory damages in the amount of $250 for each Plaintiff, plus reasonable attorneys' fees and any other just and proper relief available under Mich. Comp. Laws § 445.911.

261. Plaintiffs also seek punitive damages because Defendants Takeda and Eli Lilly carried out despicable conduct with willful and conscious disregard of the rights and safety of others. Defendants Takeda and Eli Lilly maliciously and egregiously promoted and marketed Actos, as described herein, thus increasing profits at the expense of consumers, including Plaintiffs' Assignors. Defendants Takeda and Eli Lilly promoted and marketed Actos without regard for the impact on consumers including Plaintiffs' Assignors. Defendants Takeda's and Eli Lilly's conduct constitutes malice, oppression, and fraud, warranting punitive damages.

e. Minnesota Private Attorney General Statute & Consumer Fraud Act Minn. Stat. §§ 8.31, *et seq.* & § 325F.68, *et seq.*

262. The Minnesota Prevention of Consumer Fraud Act ("Minnesota CFA") prohibits "[t]he act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby ...." Minn. Stat. § 325F.69(1).

263. Actos constitutes "merchandise" within the meaning of Minn. Stat. § 325F.68(2).

264. Defendants Takeda's and Eli Lilly's conduct, as described herein, constitutes both "deceptive" acts or practices in violation of the Minnesota CFA.

265. Defendants Takeda and Eli Lilly owed and continue to owe Plaintiffs' Assignors a duty to refrain from the unfair and deceptive practices, describe herein and to disclose the true nature of their unfair and deceptive conduct.

266. Defendants Takeda and Eli Lilly knew, or should have known, that their conduct was in violation of the Minnesota CFA.

267. Despite knowing the true nature of their products and practices for years, Defendants Takeda and Eli Lilly intentionally and knowingly omitted and misrepresented material facts regarding their unfair and deceptive practices, described herein, with the intent to mislead regulators, and Plaintiffs' Assignors, and continued to engage in unfair and deceptive practices in violation of the Minnesota CFA.

268. Defendants Takeda's and Eli Lilly's unfair methods of competition and/or unfair or deceptive acts or practices were material to Plaintiffs' Assignors, and were likely to and did, in fact, deceive regulators and reasonable consumers, including Plaintiffs' Assignors.

269. As a direct and proximate result of Defendants Takeda's and Eli Lilly's statutory violations, Plaintiffs' Assignors paid for Enrollees' prescriptions of Actos and the costs associated with the adverse effects experienced by Enrollees which proximately caused Plaintiffs' Assignors injury.

270. Defendants Takeda's and Eli Lilly's violations present a continuing risk to Assignors as well as to the general public. As such, Defendants Takeda's and Eli Lilly's unlawful acts and practices complained of herein affect the public interest.

271. Pursuant to Minn. Stat. § 8.31(3)(a), Plaintiffs seek actual damages, attorneys' fees, and any other just and proper relief available under the Minnesota Private Attorney General Statute.

272. Plaintiffs also seek punitive damages under Minn. Stat. § 549.20(1)(a) given the clear and convincing evidence that Defendants Takeda's and Eli Lilly's acts show deliberate disregard for the rights or safety of others.

f. New Hampshire Consumer Protection Act N.H. Rev. Stat. Ann. § 358-A:1 through § 358-A:13

273. Plaintiffs' Assignors and Defendants are "persons"" within the definition of New Hampshire Consumer Protection Act ("NH CPA").

274. Under the NH CPA, "trade" and "commerce" include the advertising, offering for sale, sale, or distribution of any services and any property, tangible or intangible, real, personal or mixed, and any other article, commodity, or thing of value wherever situate, and includes any trade or commerce directly or indirectly affecting the people of New Hampshire.

275. Defendants Takeda's and Eli Lilly's promotion and marketing of Actos involved knowingly engaging in unfair and deceptive acts and practices in the conduct of trade and commerce in New Hampshire. Defendants unfair or deceptive acts and practices include making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions.

276. Defendants Takeda's and Eli Lilly's conduct, as described herein, constitutes "unfair methods" and "deceptive" acts or practices in violation of the NH CPA.

277. Any person injured by another's use of any method, act or practice declared unlawful under the NH CPA may bring an action for damages and for such equitable relief, including an injunction, as the court deems necessary and proper.

278. As a direct and proximate result of Defendants Takeda's and Eli Lilly's statutory violations, Plaintiffs' Assignors paid for Enrollees' prescriptions of Actos and the costs associated

with the adverse effects experienced by Enrollees which proximately caused Plaintiffs' Assignors injury.

279. Plaintiffs seek recovery in the amount of actual damages or $1,000, whichever is greater. If the court finds that the use of the method of competition or the act or practice was a willful or knowing violation of the NH CPA, Plaintiffs also seek an award as much as three times, but not less than two times, such amount.

280. Plaintiffs also seek to be awarded the costs of this suit and reasonable attorneys' fees, as determined by the Court, as well as injunctive relief.

g. New York General Business Law N.Y. Gen. Bus. Law §§ 349-350

281. Plaintiffs' Assignors are "persons," and each defendant is a "person," "firm," "corporation," or "association" within the meaning of N.Y. Gen. Bus. Law § 349 ("New York GBL").

282. The New York GBL makes unlawful "[d]eceptive acts or practices in the conduct of any business, trade or commerce.

283. Defendants Takeda's and Eli Lilly's conduct, as described herein, constitutes deceptive acts in violation of the New York GBL.

284. Defendants Takeda's and Eli Lilly's deceptive acts and practices, which were intended to mislead Plaintiffs' Assignors who purchased and/or paid for Actos, constitutes conduct directed throughout the United States and its territories, including the State of New York.

285. As a direct and proximate result of Defendants Takeda's and Eli Lilly's statutory violations, Plaintiffs' Assignors paid for Enrollees' prescriptions of Actos and the costs associated with the adverse effects experienced by Enrollees which proximately caused Plaintiffs' Assignors injury.

286. Because Defendants Takeda's and Eli Lilly's willful and knowing conduct caused actual and measurable injury, Plaintiffs seek recovery of: actual damages or $50, whichever is greater, discretionary treble damages up to $1,000, punitive damages, reasonable attorneys' fees and costs, an order enjoining Defendants Takeda's and Eli Lilly's unlawful conduct, and any other just and proper relief available under the New York GBL.

h. Pennsylvania Unfair Trade Practices and Consumer Protection Law 73 Pa. Cons. Stat. § 201-1, *et seq*.

287. Plaintiffs' Assignors and Defendants Takeda and Eli Lilly are "persons" as defined by the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL").

288. The UTPCPL prohibits "unfair or deceptive acts or practices," including "[m]aking false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions" and "[e]ngaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding."

289. Section 201–9.2(a) of the UTPCPL permits a private action for the recovery of damages for "[a]ny person who purchases or leases goods or services primarily for personal, family or household purposes and thereby suffers any ascertainable loss of money ... as a result of ... [any] act or practice declared unlawful by this act . . ."

290. Under Pennsylvania law, Plaintiffs' Assignors' purchases of Actos qualify as personal, family or household use, regardless of whether the Assignors themselves personally used the Actos or merely purchases it for their Enrollees. Pennsylvania courts have held that when TPPs, like Plaintiffs' Assignors, purchase medications on behalf of their members, and such medications were purchased for their members' personal, family and household use, the TPPs had standing to bring claims under the UTPCPL. *See In re Actiq Sales & Mktg. Practices Litig.*, 790 F. Supp. 2d 313, 326–27 (E.D. Pa. 2011).

291. All of the acts complained of herein were perpetrated by Defendants Takeda and Eli Lilly in the course of trade or commerce within the meaning of the UTPCPL.

292. Defendants Takeda's and Eli Lilly's conduct, as described herein, constitutes "deceptive acts" and "unfair" acts in violation of the UTPCPL.

293. Defendants Takeda and Eli Lilly intended for Plaintiffs' Assignors and their agents to rely on their materially deceptive practices and Plaintiffs' Assignors would purchase or pay for Actos as a consequence of the deceptive practices, including Defendants Takeda's and Eli Lilly's misleading and fraudulent marketing, and misrepresentations and omissions of material fact with respect to Actos as set forth herein. Defendants Takeda's and Eli Lilly's deceptive representations and material omissions to Plaintiffs' Assignors were and are unfair and deceptive acts and practices. Plaintiffs' Assignors were deceived by Defendants Takeda's and Eli Lilly's misrepresentations.

294. As a direct and proximate result of Defendants Takeda's and Eli Lilly's statutory violations, Plaintiffs' Assignors paid for Enrollees' prescriptions of Actos and the costs associated with the adverse effects experienced by Enrollees which proximately caused Plaintiffs' Assignors injury.

295. Defendants Takeda and Eli Lilly are liable to Plaintiffs for treble their actual damages or $100, whichever is greater, attorneys' fees, and court costs. Plaintiffs are entitled to an award of punitive damages because Defendants Takeda's and Eli Lilly's conduct was malicious, wanton, willful, oppressive, or exhibited a reckless indifference to the rights of others.

i. South Carolina Unfair Trade Practices Act S.C. Code Ann. §§ 39-5-10, *et seq.*

296. Plaintiffs' Assignors and Defendants Takeda and Eli Lilly are "person[s]" under the South Carolina Unfair Trade Practices Act ("South Carolina UTPA"). S.C. Code Ann. § 39-5-140(a).

297. Defendants Takeda and Eli Lilly promotion and marketing of Actos, as described herein, occurred in the conduct of trade or commerce as defined by the South Carolina UTPA.

298. The South Carolina UTPA defined "trade" and "commerce" as "advertising, offering for sale or distribution of any services and any property, tangible or intangible, real, personal or mixed, and any other article, commodity or thing of value wherever situate, and shall include any trade or commerce directly or indirectly affecting the people of this State." S.C. Code Ann. § 39-5-10(b).

299. The South Carolina UTPA makes unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce unlawful. § 39-5-20.

300. Defendants Takeda's and Eli Lilly's participation in the promotion and marketing of Actos, as described herein, involved unfair methods of competition and/or unfair or deceptive acts or practices in violation of the South Carolina UTPA.

301. Defendants Takeda and Eli Lilly owed and continued to owe Plaintiffs' Assignors a duty to refrain from the unfair and deceptive practices, described herein, and disclose the true nature of their promotion and marketing of Actos.

302. Defendants Takeda and Eli Lilly knew, or should have known, that their conduct was in violation of the South Carolina UTPA.

303. Defendants Takeda's and Eli Lilly's unfair methods of competition and/or unfair or deceptive acts or practices were material to Plaintiffs' Assignors, and were likely to and did, in fact, deceive regulators and reasonable consumers, including Plaintiffs' Assignors.

304. As a direct and proximate result of Defendants Takeda's and Eli Lilly's statutory violations, Plaintiffs' Assignors paid for Enrollees' prescriptions of Actos and the costs associated

with the adverse effects experienced by Enrollees which proximately caused Plaintiffs' Assignors injury.

305. Because Defendants Takeda's and Eli Lilly's unfair methods of competition and/or unfair and deceptive practices caused actual harm to Plaintiffs, Plaintiffs seek recovery of actual damages or $200, whichever is greater, discretionary punitive damages, reasonable attorney's fees and costs, injunctive relief, and all other proper and just relief available under the South Carolina UTPA.

j. South Dakota Deceptive Trade Practices and Consumer Protection Law S.D. Codified Laws § 37-24-1 through § 37-24-35

306. Plaintiffs' Assignors and Defendants Takeda and Eli Lilly are "persons" as defined by the South Dakota Trade Practices and Consumer Protection Law ("South Dakota DTPCPL").

307. Under the South Dakota DTPCPL: "goods or services," are goods or services purchased, leased, or rented, "merchandise" includes any object, wares, goods, commodity, intangible, instruction, or service, and "trade" and "commerce" include the advertising, offering for sale, attempting to sell, selling, or distributing of any services, or any property, tangible or intangible, personal, or mixed, or of any other article, commodity, or thing of value wherever situate, for cash, exchange of goods or services, or on credit, and include any trade or commerce directly or indirectly affecting the people of this state.

308. Defendants Takeda and Eli Lilly are "sellers" as defined by the South Dakota DTPCPL.

309. The South Dakota DTPCPL broadly prohibits, among other things, knowingly acting, using, or employing any deceptive act or practice, fraud, false pretense, false promises, or misrepresentation or to conceal, suppress, or omit any material fact in connection with the sale or

advertisement of any merchandise, regardless of whether any person has in fact been misled, deceived, or damaged thereby.

310. Defendants Takeda's and Eli Lilly's conduct, as described herein, were conducted in the course of trade or commerce as defined by the South Dakota DTPCPL.

311. Defendants Takeda's and Eli Lilly's conduct, as described herein, constitutes "deceptive acts" in violation the South Dakota DTPCPL.

312. Plaintiffs' Assignors have been adversely affected by Defendants' violations of the South Dakota DTPCPL; accordingly, Plaintiffs have standing to bring a claim under the South Dakota DTPCPL.

313. As a direct and proximate result of Defendants Takeda's and Eli Lilly's statutory violations, Plaintiffs' Assignors paid for Enrollees' prescriptions of Actos and the costs associated with the adverse effects experienced by Enrollees which proximately caused Plaintiffs' Assignors injury.

Fourth Cause of Action

Fraud/Negligent Misrepresentation

314. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

315. Defendants Takeda and Eli Lilly made or caused to be made false and fraudulent representations of material facts and failed to disclose material facts to Plaintiffs' Assignors regarding the safety and efficacy of Actos.

316. Defendants Takeda and Eli Lilly misrepresented material facts, including the material misrepresentations that Actos was superior to other OADs.

317. Defendants Takeda and Eli Lilly failed to disclose the material fact that Actos caused bladder cancer.

318. Defendants Takeda's and Eli Lilly's misrepresentations fraudulently induced Plaintiffs' Assignors to include Actos in their formularies, which were used as the basis for causing them to pay for Actos. Defendants Takeda and Eli Lilly, had reason to know, or should have known that Actos caused bladder cancer, CHF, and other adverse side effects. Plaintiffs' Assignors would not have paid any amounts of money related to Actos if they had known the truth.

319. Defendants Takeda and Eli Lilly knew, recklessly disregarded, or should have known, that their misrepresentations were materially false or misleading or that their failure to disclose material facts rendered their representations false or misleading.

320. Defendants Takeda and Eli Lilly also knew, recklessly disregarded, or should have known, that their material misrepresentations and omissions would induce Plaintiffs' Assignors to pay some or all of the cost of Actos and the costs associated with the adverse effects experienced by Enrollees.

321. Defendants Takeda's and Eli Lilly's misrepresentations and omissions were material.

322. Defendants Takeda and Eli Lilly made their misrepresentations and omissions with the intent to induce Plaintiffs' Assignors to pay for Actos and the costs associated with the adverse effects experienced by Enrollees.

323. But for Defendants Takeda's and Eli Lilly's misrepresentations and omission, Plaintiffs' Assignors would not have paid for Actos and the costs associated with the adverse effects experienced by Enrollees.

324. Plaintiffs' Assignors reasonably relied on Defendants Takeda's and Eli Lilly's material misrepresentations and omissions. Defendants Takeda's and Eli Lilly's identical or substantially identical misrepresentations and omissions were communicated to Plaintiffs'

Assignors through product labeling, marketing materials, and other public statements by Defendants Takeda and Eli Lilly. But- for Defendants Takeda's and Eli Lilly's unlawful conduct, Plaintiffs' Assignors would have included Actos in their formulary, nor paid any amount of money for Actos and the costs associated with the adverse effects experienced by Enrollees.

325. Plaintiffs have been damaged by Defendants Takeda's and Eli Lilly's misrepresentations and omissions as alleged herein.

Fifth Cause of Action

Unjust Enrichment

326. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

California Unjust Enrichment

327. Plaintiffs' Assignor conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

328. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

329. Defendants Takeda and Eli Lilly have received and unjustifiably retained benefits from Plaintiffs' Assignors, in the form of costs paid, *inter alia,* and inequity has resulted.

330. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

331. Because Defendants Takeda and Eli Lilly concealed their fraud and deception, Plaintiffs' Assignors were not aware of the true facts concerning their unlawful promotion and marketing of Actos and did not benefit from Defendants Takeda's and Eli Lilly's misconduct.

332. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

333. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Colorado Unjust Enrichment

334. Plaintiffs' Assignor conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

335. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

336. Defendants Takeda and Eli Lilly have received and unjustifiably retained benefits from Plaintiffs' Assignors, in the form of costs paid, inter alia, and inequity has resulted.

337. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

338. Because Defendants Takeda and Eli Lilly concealed their fraud and deception, Plaintiffs' Assignors were not aware of the true facts concerning their unlawful promotion and marketing of Actos and did not benefit from Defendants Takeda's and Eli Lilly's misconduct.

339. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

340. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Connecticut Unjust Enrichment

341. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos.

342. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, inter alia, and inequity has resulted.

343. Because Defendants Takeda and Eli Lilly concealed their fraud and deception, Plaintiffs' Assignors were not aware of the true facts concerning their unlawful promotion and marketing of Actos and did not benefit from Defendants Takeda's and Eli Lilly's misconduct.

344. It is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

345. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

346. As a result of Defendants Takeda's and Eli Lilly's misconduct, the amount of their unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Georgia Unjust Enrichment

347. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos.

348. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, inter alia, and inequity has resulted.

349. Because Defendants Takeda and Eli Lilly concealed their fraud and deception, Plaintiffs' Assignors were not aware of the true facts concerning their unlawful promotion and marketing of Actos and did not benefit from Defendants Takeda's and Eli Lilly's misconduct.

350. It is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

351. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

352. As a result of Defendants Takeda's and Eli Lilly's misconduct, the amount of their unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Indiana Unjust Enrichment

353. Plaintiffs' Assignors conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

354. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in the unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

355. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, inter alia, and inequity has resulted.

356. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-

party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

357. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

358. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Iowa Unjust Enrichment

359. Plaintiffs' Assignor conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

360. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in the unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

361. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, inter alia, and inequity has resulted.

362. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

363. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

364. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Maine Unjust Enrichment

365. Plaintiffs' Assignors conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

366. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

367. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, inter alia, and inequity has resulted.

368. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

369. Because Defendants Takeda and Eli Lilly concealed their fraud and deception, Plaintiffs' Assignors were not aware of the true facts concerning their unlawful promotion and marketing of Actos and did not benefit from Defendants Takeda's and Eli Lilly's misconduct.

370. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

371. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Maryland Unjust Enrichment

372. Plaintiffs' Assignors conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

373. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in the unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

374. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, inter alia, and inequity has resulted.

375. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

376. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

377. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Massachusetts Unjust Enrichment

378. Plaintiffs' Assignor conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

379. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in the unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

380. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, inter alia, and inequity has resulted.

381. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

382. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

383. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Michigan Unjust Enrichment

384. Plaintiff's Assignor conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

385. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

386. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, *inter alia,* and inequity has resulted.

387. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

388. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

389. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Minnesota Unjust Enrichment

390. Plaintiff's Assignor conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

391. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

392. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, inter alia, and inequity has resulted.

393. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

394. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

395. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Mississippi Unjust Enrichment

396. Plaintiff's Assignor conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

397. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

398. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, *inter alia*, and inequity has resulted.

399. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

400. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

401. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Missouri Unjust Enrichment

402. Plaintiffs' Assignors conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

403. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

404. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, *inter alia*, and inequity has resulted.

405. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

406. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

407. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

New Hampshire Unjust Enrichment

408. Defendants Takeda and Eli Lilly have benefitted at the expense of Plaintiff's Assignor from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos.

409. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, *inter alia*, and inequity has resulted.

410. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

411. It is against equity and good conscience to permit Defendants Takeda and Eli Lilly to retain the unjust benefits of their unlawful promotion and marketing of Actos.

412. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

New York Unjust Enrichment

413. Defendants Takeda and Eli Lilly have benefitted at the expense of Plaintiffs' Assignors from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos.

414. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, inter alia, and inequity has resulted.

415. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

416. It is against equity and good conscience to permit Defendants Takeda and Eli Lilly to retain the unjust benefits of their unlawful promotion and marketing of Actos.

417. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

North Carolina Unjust Enrichment

418. Plaintiffs' Assignors conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos. The benefit conferred by Plaintiffs' Assignors was not gratuitous or by an interference in Defendants Takeda's and Eli Lilly's affairs.

419. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated, had knowledge of and consciously accepted the benefit conferred.

420. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, *inter alia*, and inequity has resulted.

421. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

422. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

423. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Oregon Unjust Enrichment

424. Plaintiffs' Assignors conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

425. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

426. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, *inter alia*, and inequity has resulted.

427. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

428. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

429. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Pennsylvania Unjust Enrichment

430. Plaintiffs' Assignors conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

431. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

432. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, *inter alia*, and inequity has resulted.

433. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

434. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

435. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Puerto Rico Unjust Enrichment

436. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly were aware that they were receiving a benefit. Defendants Takeda's and Eli Lilly's enrichment was to the detriment of Plaintiffs' Assignors.

437. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, *inter alia*, and inequity has resulted.

438. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable for Defendants Takeda and Eli Lilly to retain these benefits.

439. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

440. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Rhode Island Unjust Enrichment

441. Plaintiff's Assignor conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

442. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

443. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, *inter alia*, and inequity has resulted.

444. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

445. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

446. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

South Carolina Unjust Enrichment

447. Plaintiff's Assignor conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

448. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

449. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, *inter alia*, and inequity has resulted.

450. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

451. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

452. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

South Dakota Unjust Enrichment

453. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly were aware that they were receiving a benefit.

454. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiff's Assignor, in the form of costs paid, inter alia, and inequity has resulted.

455. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable for Defendants Takeda and Eli Lilly to retain these benefits.

456. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

457. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Texas Unjust Enrichment

458. Defendants Takeda and Eli Lilly have benefitted from fraudulently selling, setting prices for and taking part in their unlawful and fraudulent promotion and marketing of Actos. Defendants Takeda and Eli Lilly were aware that they were receiving a benefit.

459. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiff's Assignor, in the form of costs paid, *inter alia*, and inequity has resulted.

460. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable for Defendants Takeda and Eli Lilly to retain these benefits.

461. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

462. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Washington Unjust Enrichment

463. Plaintiff's Assignor conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

464. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in their unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

465. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, *inter alia*, and inequity has resulted.

466. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

467. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of their unlawful promotion and marketing of Actos.

468. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

Wisconsin Unjust Enrichment

469. Plaintiffs' Assignors conferred a benefit on Defendants Takeda and Eli Lilly by purchasing and/or providing reimbursement for Actos as a result of their unlawful promotion and marketing of Actos.

470. Defendants Takeda and Eli Lilly have benefitted from selling, setting prices for and taking part in the unlawful promotion and marketing of Actos. Defendants Takeda and Eli Lilly appreciated and had knowledge of the benefit conferred.

471. Defendants Takeda and Eli Lilly have received and retained unjust benefits from Plaintiffs' Assignors, in the form of costs paid, inter alia, and inequity has resulted.

472. Defendants Takeda and Eli Lilly have unfairly and unjustly profited from participation in, and failure to disclose, their unlawful promotion and marketing of Actos to third-party payers including Plaintiffs' Assignors; therefore, it is inequitable and unconscionable for Defendants Takeda and Eli Lilly to retain these benefits.

473. Defendants Takeda and Eli Lilly knowingly accepted and retained the unjust benefits of unlawful promotion and marketing of Actos.

474. The amount of Defendants Takeda's and Eli Lilly's unjust enrichment should be disgorged and returned to Plaintiffs, in an amount to be proven at trial.

IX. Prayer for Relief

475. Plaintiffs pray for the following relief:

(a) On Plaintiffs' RICO claims, compensatory damages, and punitive damages for the damages Plaintiffs' Assignors have sustained as a result of Defendants Takeda's and Eli Lilly's conduct as may be permitted under the relevant statutes, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorneys' fees;

(b) On Plaintiffs' Consumer Fraud Act claims, compensatory damages, and punitive damages for the damages Plaintiffs' Assignors have sustained as a result of Defendants Takeda's and Eli Lilly's conduct as may be permitted under the relevant statutes, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorneys' fees;

(c) On Plaintiffs' Fraud/Negligent Misrepresentation claims, compensatory damages, and punitive damages for the damages Plaintiffs' Assignors have sustained as a result of Defendant Takeda's and Eli Lilly's conduct as may be permitted under the relevant statutes, such amount to be determined at trial, plus Plaintiffs' cost in this suit, including reasonable attorneys' fees;

(d) On Plaintiffs' claim for unjust enrichment, recovery in the amount of Plaintiffs' Assignors payment for Actos, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorneys' fees;

(e) For an order otherwise requiring Defendants Takeda and Eli Lilly to refund and make restitution on all monies acquired from the sale of Actos to Plaintiffs' Assignors;

(f) Awarding Plaintiffs prejudgment interest on all damages;

(g) Awarding Plaintiffs their costs and expenses in this litigation, including reasonable attorneys' fees and expert fees; and

(h) Awarding Plaintiffs such other and further relief as may be just and proper under the circumstances.

X. JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs demand trial by jury on all issues so triable.

Respectfully Submitted,

Attorneys for Plaintiffs

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